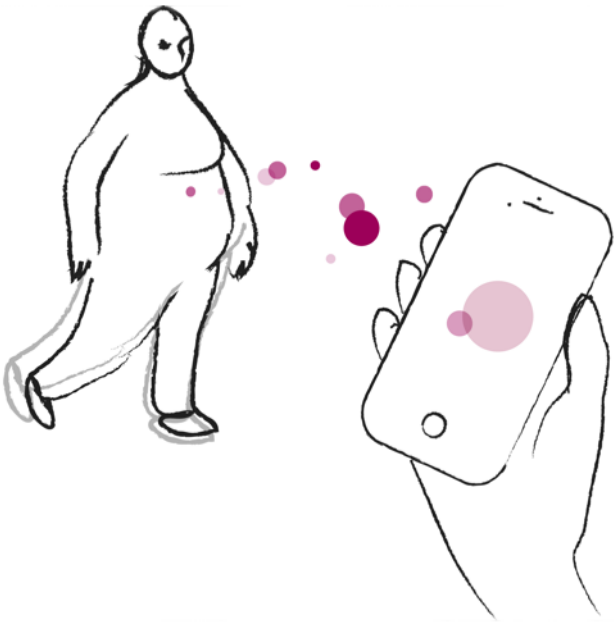
Thesis for doctoral degree (Ph.D.)
2020

Next in bariatric surgery – the role of lifestyle and adequate information to improve patients' quality of life and health



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Karolinska Institutet

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Next in bariatric surgery – the role of lifestyle and adequate information to improve patients' quality of life and health
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Institutionen för Medicin, Solna, Enheten för Klinisk epidemiologi

Next in bariatric surgery – the role of lifestyle and adequate information to improve patients' quality of life and health

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ABSTRACT

Aim: The overall aim of this doctoral thesis is to increase the knowledge about how behavioral modification and information can improve the individual results following bariatric surgery or conventional weight loss treatment.

Background: Obesity is a growing health issue often affecting quality of life and morbidity. Bariatric surgery is since many years acknowledged to lead to successful long-term weight loss. Its effect on weight loss is more pronounced in the beginning post-surgery and thereafter some weight regain is to be expected. To counteract this, it is of importance to explore possible ways to support lifestyle changes among patients who choose to undergo bariatric surgery. Digital solutions may be useful in supporting lifestyle changes pre- or post-surgery, but they have to be scientifically evaluated.

Methods and materials: In Paper I, 250 women with obesity from Finland, Norway, Germany, Sweden and the Netherlands were asked about their main reasons to seek surgery and their expectation on post-surgery weight loss result. In Paper II, at 1-year post-surgery the Swedish participants from paper I (n=50) were asked which issue they felt most satisfied with post-surgery, and if they were satisfied with their post-surgery weight loss. In Paper III, a cohort of 23,233 persons were recruited within a Web-based weight loss program (viktklubb.se) and the participants eating behavior were measured with TFEQ-R18 at baseline, 3- and 6-months. In Paper IV, 146 out of 201 patients accepted for bariatric surgery were randomized either to standard care or to standard care plus a 3-month-smartphone app intervention to increase their level of moderate-to-vigorous physical activity post-surgery.

Results: The main reason to seek bariatric surgery was weight loss. The odds ratio for certain reasons like less co-morbidity, less medication, and longevity was dependent on if the participants had co-morbidities. The participants expected to lose almost 80% of their excessive weight post-surgery. The issue of most satisfaction 1-year post-surgery was improved self-esteem. Only those with a weight loss of more than 80% of their excessive weight were satisfied with their post-surgery weight loss. A change in eating behavior was associated with a greater weight loss in the Web-based weight loss program. The uncontrolled eating score decreased and the cognitive restrained eating score increased in both men and women, whereas a reduction in the emotional eating score only was seen among men. A smartphone app intervention led to a significant increase in minutes/day of moderate-to-vigorous physical activity in the intervention group, compared to the control group receiving standard care post-surgery.

Conclusions: To address patient expectations before bariatric surgery may improve post-surgery satisfaction. Individualized pre-surgery information and post-surgery care could be of importance for the lifestyle changes required after bariatric surgery. Technology like Web-based or app-based programs may serve as interactive solutions to support lifestyle changes and the need for individualized information.

To Anna, Erik and Jörgen

LIST OF SCIENTIFIC PAPERS

I. **Women's reasons to seek bariatric surgery and their expectations on the surgery outcome - A multicenter study from five European countries**
Mari Hult, MD, Stephanie E. Bonn, PhD, Wouter te Riele, MD, PhD, Lars Fischer, MD, PhD, Signe Röstad, MD, Kai Orava, MD, Timo Heikkinen, MD, PhD, Rune Sandbu, MD, PhD and Anne Juuti, MD, PhD
Submitted manuscript

II. **Women's Satisfaction with and Reasons to Seek Bariatric Surgery—a Prospective Study in Sweden with 1-Year Follow-up**
Mari Hult, MD, Stephanie E. Bonn, PhD, Lena Brandt, MSc, Mikael Wirén, MD, Phd, Ylva Trolle Lagerros, MD, PhD
Obesity Surgery 2019
https://doi.org/10.1007/s11695-019-03834-3

III. **The Change in Eating Behaviors in a Web-Based Weight Loss Program: A Longitudinal Analysis of Study Completers**
Madeleine Svensson, PhD; Mari Hult, MD; Marianne van der Mark, PhD; Alessandra Grotta, PhD; Josefine Jonasson, MSc; Yvonne von Hausswolff-Juhlin, MD, PhD; Stephan Rössner, MD, PhD; Ylva Trolle Lagerros, MD,PhD
Journal of Medical Internet Research 2014;16(11):e234)
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IV. **Can app technology increase physical activity after bariatric surgery? Results from the PromMera study, a randomized controlled trial**
Mari Hult, MD, Stephanie E. Bonn, PhD, Kristina Spetz, MSc, Helén Eke, MSc, Ellen Andersson, MD, PhD, Mikael Wirén, MD, PhD, Marie Löf, Prof, Ylva Trolle Lagerros, MD, PhD
Submitted manuscript

RELATED PUBLICATIONS

(Not included in the thesis)

App technology to support physical activity and intake of vitamins and minerals after bariatric surgery – Protocol for the PromMera-study: a randomized controlled clinical trial
Stephanie E. Bonn, PhD; Mari Hult, MD; Kristina Spetz, MSc; Marie Löf, Prof; Ellen Andersson, MD, PhD; Mikael Wirén, MD, PhD; Ylva Trolle Lagerros, MD, PhD

Manuscript accepted to **JMIR Research Protocols**

CONTENTS

LIST OF ABBREVIATIONS

%EBMIL	Percentage Excess BMI loss
EORTC	European Organization of Research and Treatment of Cancer
%EWL	Percentage Excess Weight Loss
%TWL	Percentage Total Weight Loss
BMI	Body Mass Index
BCT	Behavior Change Theory
BodPod®	Air displacement plethysmograph
BP	Bodily Pain (SF-36)
BPD-DS	Biliopancreatic diversion and duodenal switch
cpm	Counts per minute
CCK	Cholecystokinin
GH	General Health (SF-36)
GIP	Gastro Inhibitor Peptide
GLP-1	Glucagon Like Peptide-1
HRQoL	Health-Related Quality of Life
LSG	Laparoscopic Sleeve Gastrectomy
LPA	Light Physical activity
MCS	Mental Component Summary score (SF-36)
MH	Mental Health (SF-36)
MVPA	Moderate-to-Vigorous Physical Activity
PF	Physical Function (SF-36)
PCA	Physical Component Summary score (SF-36)
PYY	Petide YY
RCT	Randomized Controlled Trial
RE	Role limitations due to an emotional problem
RP	Role limitations due to Physical problems
RYGB	Roux-en-Y Gastric Bypass
SCB	Statistiska Central Byrån (Statistics Sweden)
SD	Standard Deviation
SE	Standard Error

SF-36	36-item Short Form Health Survey
SF	Social Function (SF-36)
SOReg	Scandinavian Obesity Surgery Registry
SOS	Swedish Obese Subjects study
TFEQ	Three-Factor Eating Questionnaire
TFEQ-CR	TFEQ-Cognitive Restraint
TFEQ-EE	TFEQ-Emotional Eating
TFEQ-UE	TFEQ-Uncontrolled Eating
VT	Vitality (SF-36)
WHO	World Health Organization

1 BACKGROUND

1.1 OBESITY – IN A GLOBAL PERSPECTIVE

Obesity is recognized as a considerable risk factor for health, and it was classified as a disease by the World Health Organization (WHO) as early as 1948. Obesity rates are steadily increasing and according to the WHO, obesity has almost tripled globally since 1975. In 2016, 13% of adults over 18 years were obese and 39% were overweight (1). The definition of overweight is a BMI between 25 and 30 kg/m^2 and for obesity BMI ≥30 kg/m^2. Persons with overweight/obese have a severely increased risk of developing weight related diseases and a higher mortality related to these than individuals of what is considered normal weight. Obesity increases the risk of a number of diseases, such as type 2 diabetes, cardiovascular diseases, musculoskeletal disorders, fatty liver disease, and some cancers. Mortality is related to the co-morbidities, such as insulin resistance, type 2 diabetes, hypertension, dyslipidemia and obstructive sleep apnoea. WHO states that today, most people in the world lives in countries where overweight and obesity is a larger killer than underweight (1-3).

Table 1. *Classification of obesity according to the World Health Organization*

Classification	**BMI (kg/m^2)**	
	Principal cut-off points	**Additional cut-off points**
Underweight	**<18.50**	**<18.50**
Normal range	**18.50 - 24.99**	**18.50 - 22.99**
		23.00 - 24.99
Overweight	**≥25.00**	**≥25.00**
Pre-obese	25.00 - 29.99	25.00 - 27.49
		27.50 - 29.99
Obese	**≥30.00**	**≥30.00**
Obese class I	30.00 - 34.99	30.00 - 32.49
		32.50 - 34.99
Obese class II	35.00 - 39.99	35.00 - 37.49
		37.50 - 39.99
Obese class III	≥40.00	≥40.00

Source: Adapted from WHO, 1995, WHO, 2000 and WHO 2004.

1.2 OBESITY IN SWEDEN

According to The Public Health Agency of Sweden, overweight and obesity have increased in all age groups in Sweden from 2006 to 2018 and 51% of the population between 16 to 84 years of age reported weight and height corresponding to overweight or obesity. The group with the most increase in weight were those between 16 to 29 years of age, even though overweight and obesity is more common in higher age groups. In 2018, obesity was more common among those with only elementary school (22%) and high school education (20%), compared to those with higher education (12%). There was still a significant gender difference in the group with overweight/obesity, men (58%) and women (45%), after adjustment for education, country of birth and region, but there was no significant difference in obesity (BMI>30 kg/m^2), 16% respectively 15%.

Figure 1. *Overweight/obesity change in age groups (From the website of Public Health Agency of Sweden)*

Hemmingsson et al. (4), reports that the increase of severe obesity in Sweden was 153% during the period 1995 to 2017, obesity and overweight increased 86% respectively 24% during the same period. Still, the prevalence in Sweden was low compared to the rest of Europe. Lower education and living in rural areas were found to be prognostic variables and may be important to take into consideration for public health professionals working with prevention.

1.3 BARIATRIC AND METABOLIC SURGERY

The history of bariatric and metabolic surgery started in the 1950s when surgeons observed that individuals with obesity that had a larger portion of their small bowel removed lost weight and the weight loss was long term (5, 6).

The jejunocolic bypass

Among the first procedures were the jejunocolic bypass and end-to-side jejunoileal bypass, see Figure 2, that gave a good weight loss (7). In the 1960s and early 1970s reports with successful results from jejunocolic bypass and end-to-side jejunoileal bypass were published, but severe side effects were also reported, i.e. development of liver failure. There was a risk of bacterial overgrowth in the blind loop which could contribute to bacterial translocation and liver disease. There was also a risk of malabsorption like malnutrition, vitamin deficiency (mostly fat-soluble) and electrolyte abnormalities.

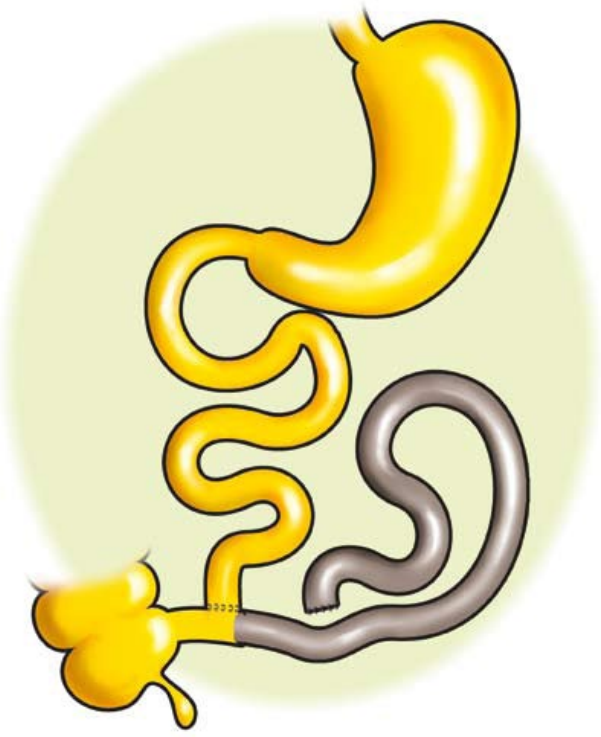


Figure 2. *The jejunoileal bypass by Payne (1969)*

The biliopancreatic diversion with duodenal switch

The biliopancreatic diversion, see Figure 3, that Scopinaro developed 1979 has been modified with a duodenal switch resulting in a dramatic weight loss even for the group with a BMI >50-60 kg/m^2 (8). However, these patients need lifelong thorough monitoring of their medication and supplement of vitamins and minerals to a much larger extent than those after gastric bypass.

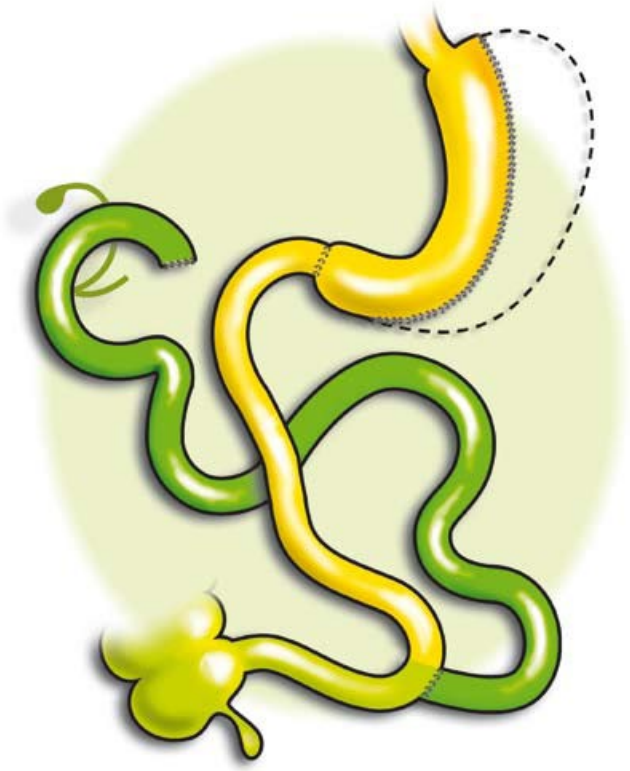


Figure 3. *The biliopancreatic diversion with duodenal switch*

The development of gastric restrictive procedures

During the 1960s it was observed that patients who had a gastric resection for gastric or duodenal ulcers lost weight and experienced a sustained weight loss (9). This led to the development of solely restrictive procedures like gastric partition, vertical partition with a silicon band, vertical gastric banding, see Figure 4, adjustable gastric banding and sleeve gastrectomy.

Figure 4. *The Vertical Banded Gastroplasty (VBG)*

The Roux-en-Y Gastric Bypass (RYGB)

The bariatric procedures have been divided into primarily malabsorptive or restrictive procedures. The bowel shunting procedures are classified as malabsorptive and vertical banding and adjustable banding are classified as restrictive. The procedure with a side-to-side anastomosis between the fundus of the stomach and a loop of the jejunum, where the stomach was divided below the anastomosis was created by Mason 1967. This was the precursor of the gastric bypass, see Figure 5, that has been the dominating bariatric procedure globally in the last three decades (9).

Figure 5. *The Roux-en-Y Gastric Bypass (RYGB)*

The Laparoscopic Sleeve Gastrectomy (LSG)

During the last ten years the sleeve gastrectomy, see Figure 6, has grown more popular. This was originally the first step in the duodenal switch for the patients with obesity class III (BMI>50 kg/m^2), but has now developed into a stand-alone procedure. The sleeve has the advantage of a simpler surgical technique and a sufficient weight loss to resolve co-morbidity. Additionally, if the patient experience weight regain, conversion into a gastric bypass is possible. In 2018, 45.6% of the bariatric procedures in Sweden were Laparoscopic Sleeve Gastrectomy (LSG) and 51.1% were laparoscopic gastric bypass (10).

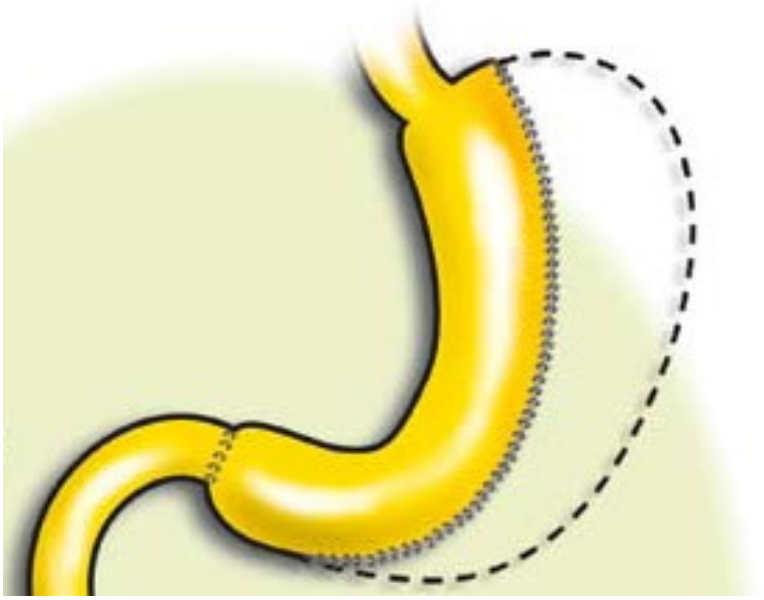
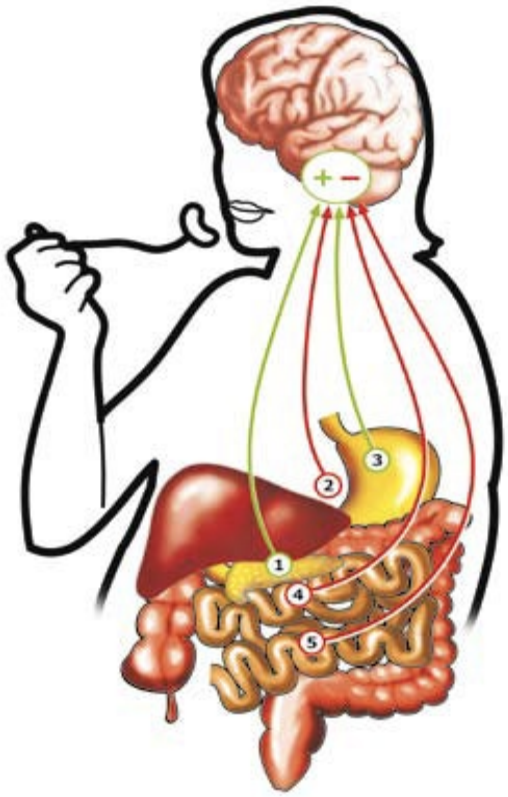


Figure 6. *The Laparoscopic Sleeve Gastrectomy (LSG)*

Hormonal effects

Roux-en-Y Gastric Bypass has been considered to be both restrictive and malabsorptive. However, the hormonal effects of gastrointestinal peptides like GLP-1, leading to earlier satiety, less hunger and probably healthier choice of food, are now considered more important to understand the sustained weight loss over time, see Figure 7. This hormonal effect is also seen after the sleeve gastrectomy.



1. Insulin
2. Vagus
3. Ghrelin
4. CCK/GIP
5. PYY, GLP-1

Figure 7. *The gut and the brain. Insulin and ghrelin stimulate the appetite. Actions to decrease the appetite comes from cholecystokinin (CCK) and gastric inhibitor peptide (GIP) secreted in the foregut and peptide YY (PYY) and glucagon like peptide-1 (GLP-1) secreted in the hindgut. The afferent stimuli from the vagus nerve gives experience of satiety.*

It was not until 1991 that the National Institutes of Health (NIH) consensus conference acknowledged the effect of bariatric surgery in reduced co-morbidities (11). Thereby, the benefit for the patients were recognized as greater than the risk of surgery. Bariatric surgery is now acknowledged to be the only method resulting in maintenance of marked weight loss and risk reduction for the persons with obesity (12-14).

Surgical complications and morbidity

The minimally invasive surgical technique started in the 1990s and revolutionized the area of bariatric surgery with reduced morbidity and mortality in bariatric patients. The new technique also resulted in reduced number of days in hospital. The first laparoscopic RYGB was performed 1993. The mortality in laparoscopic bariatric surgery decreased from 1% to 0.2% and complications related to surgery were reduced to a third compared to open surgery, see Figure 8. In 2018, 99% of all bariatric procedures in Sweden were performed laparoscopically (10).

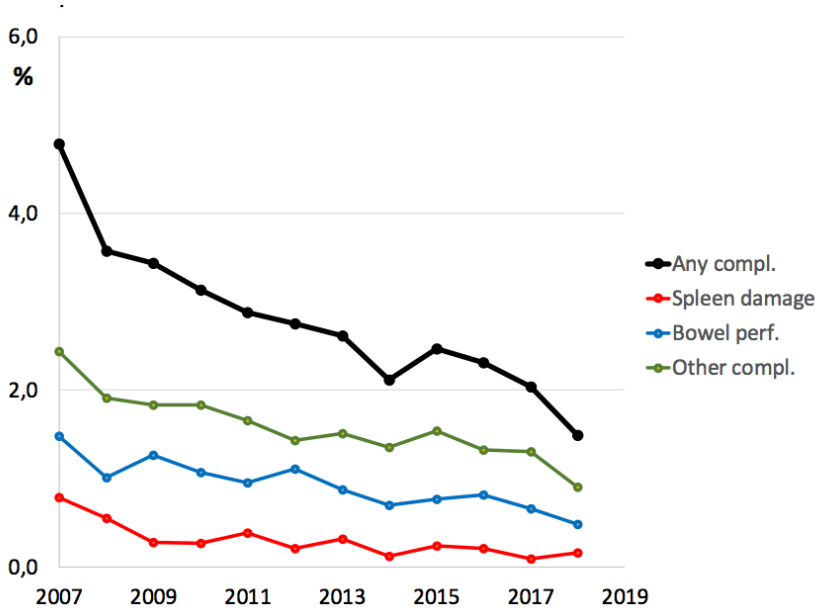


Figure 8. *Perioperative complications to bariatric procedures from 2007 to 2018 in Sweden according to SOReg, the Swedish national register of quality in bariatric surgery.*

Lifestyle changes after surgery

Lifestyle changes, including increased physical activity, are highly recommended to optimize postoperative outcomes. Generally, adults are recommended to be moderately to vigorously physically active for 30 minutes at least 5 days a week (15) and the European Association for the Study of Obesity (EASO) recommendation is at least 150 minutes/week of moderate physical activity for post-bariatric surgery patients with a goal of 300 minutes/week (16).

However, among the general population of middle-aged adults in Sweden, less than 65% reach the recommendation of moderate physical activity 150 min/week according to Statistics Sweden (17). If you increase the level of physical activity over the recommended level you will increase the positive effect on weight loss and health benefits. Bariatric surgery has also been shown to improve health related quality of life early post-surgery which has been used as an argument for carrying out this type of surgery (18, 19).

1.4 EATING BEHAVIOR

The obesity epidemic is complex and the reasons for obesity is acknowledge to be multifactorial. There are evidence suggesting that 50 to 80% of obesity can be referred to genetics factors but there is still a link to lifestyle factors like eating behavior and a more sedentary lifestyle (20). Eating behavior became a topic of interest among researchers when the global obesity epidemic took off. One of the first questionnaires to study eating behavior was published by Meyer & Poodle 1977 (21). It was called the Latent Obesity Questionnaire, LOQ. The theory behind the questionnaire was based on that there are three kinds of people; obese, non-obese and non-obese with the same eating behavior as obese, so called latent obese. The latent obese individuals are biologically programmed to become obese, but manages to maintain a normal weight by limiting (restraining) their food intake. In addition to a questionnaire with 40 items, a test meal requiring 20 minutes, where food intake per time unit was registered, was included.

Some years previously another theory was tried in a questionnaire, The Restraint Scale, RS, by Herman & Polivy (22). It contained 10 items to assess food intake in relation to three different stimuli:

1. Preload of food - how does a person react after a high-calorie milkshake? With overeating or limitation (restrain)? According to Herman's theory, the restraint eaters would react with "counter-regulation" and overeat.

2. Counter-regulation would represent a form of Disinhibition. Loss of control was detected with a classic disinhibitor i.e. alcohol. Restrained eaters increased their food intake during the influence of alcohol, unlike unrestrained eaters.

3. Emotional Disinhibitors, such as worry, anxiety, and depression. These conditions resulted in a higher extent of overeating in restrained eaters, than in unrestrained eaters.

The development of Three Factor Eating Questionnaire (TFEQ)

The researchers Stunkard and Messick saw that both the LOQ and RS had their weaknesses. The LOQ had difficulty to comprise the group “restrained obese” because it had two dimensions. Restraint vs. unrestraint and partly obese vs. non-obese. It was also difficult to conduct this test without proper test meal laboratory equipment. Concerning the RS

questionnaire, several studies pointed out problems. In particular, the predictive validity and the construct validity. First the questionnaire could not predict the eating behavior in obese individuals with regards to overeating after preload. Four studies (23-26), demonstrated that no overeating after preload was seen, whereas in one study (24), they found that the obese group actually ate less after the preload. The second problem concerned the construct validity. Four studies (27-30) reported that the questionnaire did not only measure the "dietary restrain", but also another construct, namely weight change (weight fluctuation). Social desirability was significantly correlated to scores from the RS in the obese group, but not the normal weight group. The authors concluded that both weight fluctuation and social desirability were confounders for construct validity in obese persons evaluated using the RS questionnaire.

Later on, the LOQ and RS questionnaires were combined by Stunkard and Messick. In addition to the RS's 10 items and the LOQ's 40 items, 17 new items were added. With these items, a factor analysis was done in which three factors crystalized: Factor I interpreted as cognitive control of eating behaviour, Factor II as disinhibition to hunger and Factor III as susceptibility to hunger. When these three were combined, there was a correlation to patients' weight with a significant p-value <0.01.

Next, they constructed a revised 93 item form, which they later reduced to 58 items, as several items were variants of each other and the three factors were also correlated to each other in varying degrees. The 58 items form was published by Stunkard 1981 in the textbook 'The body Weight Regulatory System: Normal and Disturbed Mechanisms'. Finally, The Three Factor Eating Questionnaire (TFEQ) with 51 items, was described in an original article in 1984 (31). Additional items have now been removed, primarily those that correlated to the weight fluctuation in Factor II.

The part of the discussion in the original article reveals several opportunities to use the test in obesity treatment. i.e., patients with high scores on Factor I would particularly be more susceptible to diet information and other traditional approaches than to behavioral control. Those scoring high on Factor II would rather do well on treatment similar to addiction treatment, while those with high scores on Factor III require strategies to deal with their feelings of hunger or appetite suppressant medication.

The TFEQ has been used within the Swedish Obese Subjects, the SOS study, which included 4377 Swedish patients. In 2000, Karlsson et al. (32) published an article evaluating the construct validity of the 51 items TFEQ using data from the SOS study. Factor I, Cognitive Restraint Eating (CR), showed strong positive item-scale discriminant validity while Factor II had a weak internal structure and that Factor II and III could be grouped together into Uncontrolled eating (UE). Another factor III was identified, namely Emotional eating (EE), see Figure 9.

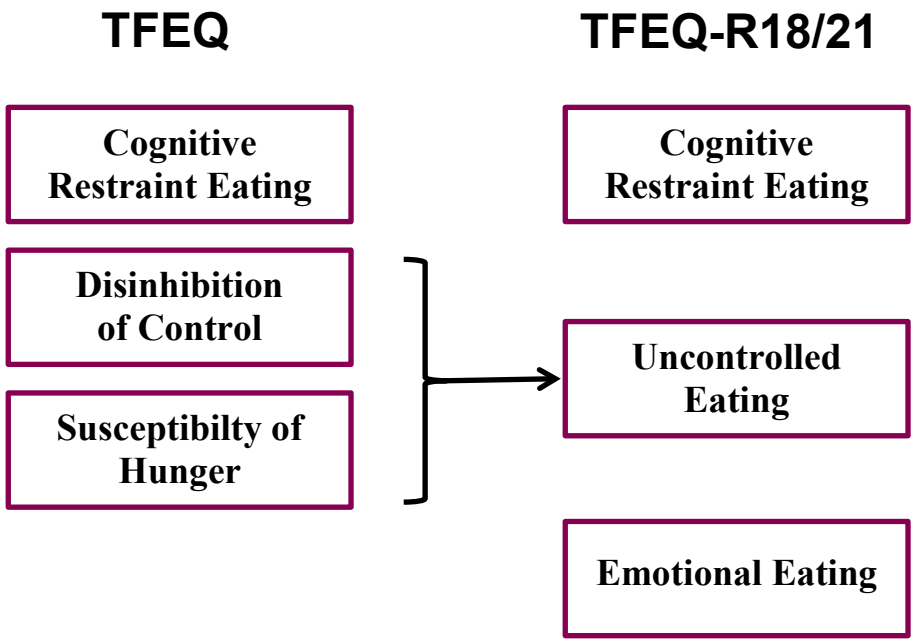


Figure 9. *Development of the Three Factor Eating Questionnaire, TFEQ*

With this new set of factors, and a reduction of the number of items to 18, they could demonstrate a better validity, and also a sufficient internal consistency.

Further development and validation of the TFEQ have been done. An addition of items resulted in TFEQ-R21 which reduced floor and ceiling effect (33). Floor and ceiling effect are demonstrated if the variables are skewed either to the bottom (floor) or the top (ceiling), therefore, the questionnaire must be appropriate for the group of respondents. The TFEQ-R21, was validated in a mixed population in France in 2004 (34). It was shown that obese individuals scored higher than the normal population at the Uncontrolled Eating and Emotional Eating (35). Anlglé validated the questionnaire in a younger female population in Finland, 2009 (36). However, in a non-European population validation by Cappelleri et al. in 2009, they found that

it was necessary to revise the TFEQ-R21 again. This resulted in TFEQ-R18v2 (37). TFEQ has been used in recent studies for the evaluation of eating behavior in patients undergoing bariatric/metabolic surgery (38).

The TFEQ can be used to see if and how a treatment/ diet/surgery alters eating behavior and is included in two of the four studies in this thesis. **Paper III**, with data collection within www.viktklubb.se including voluntarily individuals with obesity, adults in Sweden, who signed up to participate in a web-based weight loss program. Both men and women were included and eating behavior was assessed with TFEQ at baseline, 3 months and 6 months of follow up. Further, we also used TFEQ in **Project IV**, a randomized clinical trial where the aim was to explore the possibilities to encourage individuals to increase their level of physical activity after obesity surgery using new smartphone application technology. In addition to physical activity, we were also interested in studying if the intervention affected eating behavior in a positive direction.

1.5 PATIENTS MOTIVATORS AND EXPECTATIONS ON BARIATRIC SURGERY

Unrealistic pre-surgical expectations from bariatric surgery might be the most important reason for dissatisfaction with the results post-surgery. If an unrealistic amount of weight loss is the primary reasons for seeking a surgical solution, it can be important to moderate that expectation in order to improve satisfaction with postoperative weight loss and increase the ability of patients to cope with potential postoperative complications. One can speculate; if a patient were better informed would it help him or her to aim for a realistic target weight? In order to be able to inform the patients, it is imperative to explore their expectations prior to surgery.

The focus of previous studies, of which none has been performed in Europe, have mainly concentrated on patients' expectations on weight loss after surgery (39-41). Expectations on quality of life (QoL), self-image, and recovery from co-morbidities after surgery have only been explored in studies of smaller to moderate size (n ranging from 30 to 208) (42-44). Medical health was rated the overall primary reason for seeking surgery in all the studies.

Further, patients with higher QoL scores were more satisfied with their results of the treatment. However, prior studies report that unrealistic expectations were not associated with changes in psychological functioning or emotional status (45, 46).

In bariatric surgery, most patients expect to reach a weight corresponding to a BMI between 25 and 30 kg/m^2 of after surgery. Even so, this is rarely achieved (40, 47-49). To investigate this further, **Paper I and II** in this thesis aims to gather more knowledge about patients' expectations pre-surgery.

$$\%\text{EWL} = \frac{\text{Preoperative weight} - \text{Follow up weight}}{\text{Preoperative weight} - \text{Ideal weight}} \times 100$$

Figure 10. *The weight over a BMI of 25 kg/m^2 is considered to be excessive weight. The calculation of %Excessive Weight Loss in the included papers is done as above. The ideal weight is considered to be the weight at a BMI of 25 kg/m^2.*

1.6 PATIENTS' SATISFACTION POST-SURGERY

One can presume that satisfaction post-surgically would be closely related to pre-surgical expectations and the patients' satisfaction post-surgery is mostly related to their weight loss. In most studies, an excessive weight loss%, EWL%, over 80% is required to satisfy the patients (29), while an EWL% of 60% is to be considered successful weight loss post-surgery (12), see Figure 10 for %EWL calculation. Despite the mostly good results with regards to weight loss after surgery, patients are not always satisfied due to unrealistic expectations (41, 42, 50-52). However, patients undergoing non-surgical weight loss treatments have similar unrealistic expectations, but recent research has shown that in non-surgical treatment, unrealistic expectations might improve the results in short term (48, 53-55). The real challenge is to discover how to inform and educate the patients pre-surgery so that the expectations and level of satisfaction are more realistic. That may lead to more realistic goals and make the patients more settled with the result post-surgery.

In **Paper II** of this thesis, we assessed the post-surgery satisfaction in a cohort of Swedish women.

1.7 HEALTH RELATED QUALITY OF LIFE

The SF-36 is a validated questionnaire commonly used in bariatric surgery, to assess Quality of Life (18, 19, 56-61). This questionnaire was used in the Swedish Obese Subjects (SOS) study and is also part of the Swedish quality register in bariatric surgery, SOReg. All patient that undergoes bariatric surgery in Sweden is included in this register if they not oppose it. The SF-36 is included in **Paper II and IV** in this thesis.

The SF-36 comprise eight domains: physical function (PF), role limitations due to physical problem (RP), bodily pain (BP), general health (GH), vitality (VT), social function (SF), role limitations due to an emotional problem (RE), and mental health (MH). Generally, the domains are organized into to two summary scales: the physical component summary scale (PCS) and the mental component summary scale (MCS). Whereas the PCS is based on PF, RP, BP and GH, the MCS is based on VT, SF, RE, and MH. The PCS and MCS summary scales are calculated and standardized according to a norm-based scoring between 0 (poor health) and 100 (good health) with a mean of 50 and a standard deviation of 10.

It is shown that persons with obesity score lower than the general population with regards to quality of life (19, 60-62) and the scores improve in the majority of patients 1-year post-surgery (19, 60, 63). Improvements in quality of life post-surgery have even been shown as early as within three-month post-surgery (18, 19). However, studies with longer follow-up suggest that the improvement may decline over time (59, 60) and some patients might not experience an improvement in mental health at all. For example, Lagerros et al. have shown an increased risk of post-surgery self-harm and hospitalization for depression in a nationwide cohort study of patients undergoing gastric bypass (64).

Those who undergo bariatric surgery also score very low quality of life (QoL) questionnaires pre-surgery. Commonly, they score better post-surgery, but Bond et al related QoL to physical activity (PA) and saw a higher weight loss in the group that went from inactive to active. In addition, they scored better on QoL (SF36) (65).

The SF-36 is included in **Paper I, II and project IV** in this thesis. The SF-36 is well validated in individuals undergoing bariatric surgery in Sweden.

1.8 PHYSICAL ACTIVITY

In conservative treatment of obesity, a combination of diet and increased physical activity has been shown to give a more successful weight loss than diet alone (66). Three reviews since 2010 suggest that patients' physical activity after bariatric surgery does not increase as much as expected. However, patients with increased post-surgery physical activity have a more successful weight loss (67-69). Nevertheless, in the studies included, physical activity was mostly self-reported. Only two studies objectively measured physical activity using pedometers. None of the included studies used accelerometers to objectively assess physical activity.

In a publication from 2014, 12 and 18 months after bariatric surgery, the participants spent >70% of the time sedentary (70). Similarly, a Swedish publication by Berglind et al. 2016 (71), demonstrated that the self-reported increases in physical activity from pre- to post-surgery were not confirmed by an objective measurement using accelerometers. This is supported by Afshar et al. (72). Additionally, higher physical activity pre-surgery seems to predict higher physical activity post-surgery (73, 74). Long term follow-up after surgery do not give any encouraging results either, 88.5% of the women and 84.2% of the men did not reach the national recommendations of 10,000 steps/day in a Canadian sample (75). None of these studies included any intervention to improve physical activity.

In **Paper IV** of this thesis, we conducted a randomized controlled trial to see if an intervention with a smartphone application could improve the level of physical activity post-surgery. Physical activity was objectively measured at baseline and follow-ups using accelerometers. Measurement of physical activity with accelerometers are today a recommended and objective method compared to self-reported physical activity. Self-reported physical activity tends to exceed the objective measured physical activity (76). Accelerometers are reasonable easy to handle for study personnel, if you have the right software on the computer handling all the data.

Figure 11. *The triaxial Actigraph® wGT3x-BT accelerometer. The accelerometer can be worn both at the wrist and the hip.*

The triaxial Actigraph® wGT3x-BT accelerometer (Actigraph Corporation, http://actigraphcorp.com) that we used in Paper IV have a size of a bigger wrist watch and can be worn either on the hip or the wrist. In recent years, studies with the accelerometer worn on the wrist have become more common because of the possibility for the participants to wear it 24/7 and that will result in more accurate measurement with less non-wear time. If you have it worn on the hip the study participants are told to take it off during night time which can reduce compliance to wearing the accelerometer.

1.9 E-HEALTH AND M-HEALTH

WHO defines eHealth as the use of information and communication strategies for health. Within eHealth, mHealth is defined as medical or public health practice by mobile devices (77). eHealth is a new, but rapidly growing field made possible by new technology. This technology makes it possible to reach out to patients needs in a new way, where traditional health care methods cannot compete.

In today's society, easy access to any health care services are appreciated by patients. Initially, mHealth originally meant short message service, SMS, but today it has gradually transferred to applications, "apps". The applications are getting increasingly more advanced in layout, measuring (for example steps as an indication of physical activity), notices (for feedback or education) and even interaction with health care or others, trough the app. In Sweden, we have seen a dramatic increase in the use of mHealth during the last years with expansion of app based primary care like Kry, Doktor.se etc. The patients rank the easy access to a general practitioner, other medical specialist or other health care professionals very high.

A search on e.g. Appstore and Google store results in numerous new apps that turn to people with obesity before and after bariatric surgery. One example is Baritastic and another Swedish example is BariBuddy.se. These two are examples of apps that bariatric clinics can join and use for their patients pre- and post-surgery with functions like diet advise, contact with the clinic, and more. In Finland, a newly developed app will be launched in fall 2020. Hälsovikthuset.fi, is developed by the five University Hospitals of Helsinki, Turku, Tampere, Oulu and Kuopio, it is already in use on the Internet, and is apparently very much appreciated by the patients (78).

In a systematic review from 2013, the authors concluded that technology interventions comprising an educational content or/and an intervention targeting increased physical activity and weight reduction, have beneficial impact (79). The use and ownership of a smartphone is steadily increasing, in Sweden over 92% of the population own a smartphone and 90% use internet on their smartphone (80). This is independent of socioeconomic status.

When the top ranked mobile apps for physical activity were analyzed in 2013, Conroy et al. found that the apps were limited when it came to behavior change techniques, BCTs. Primarily there were two types of apps, either educational or motivational apps (81). The scientists, developers, clinicians and consumers were encouraged to engage in this matter. A co-worker to Conroy reported that self-monitoring was rare in physical activity apps compared to weight-managing apps. This could be considered a weakness, as you then only rely on technical tracking of physical activity and give less direct feedback to the user (82).

In a review by Schoeppe et al 2017, with intention to explore the relationship between app quality, technical app features and behavior change techniques (83). They concluded that most apps comprised some behavior change techniques, but the apps of higher quality (measured by a Mobile App Rating Scale, MARS) included more features and behavior change techniques in the same app.

Twenty-eight smartphone applications, specifically targeting patients undergoing obesity surgery were reviewed by Stevens et al. in 2014. Surprisingly, only 42.9% were developed by health care professionals, which one may consider a requirement for providing accurate and evidence based mHealth (84).

Web-based or app-based interventions can provide significant change in behavior. This has been demonstrated in several studies (79, 85-87). However, the follow up has been limited and some studies show that the effect of the intervention diminishes over time. The efficacy on weight loss, respectively on physical activity by mHealth, has been assessed. A systematic review and meta-analysis recently demonstrated significant changes on body weight, but not in physical activity (88).

In **Paper IV** in this thesis, we use a smartphone app PromMera as an intervention tool in a randomized controlled trial. Potentially, the construction of the app influences the interventional impact. For example, individual feedback has been shown to lead to a greater impact (89). To have a reasonable long intervention period, and long follow up time within the study seem to be of importance (90). To combine features like education, individual feedback and setting individual goals like we do in the PromMera app have support in the literature. Its effect has been, and will be, further explored in our still ongoing study.

2 AIMS

Paper I

The aim of this study was to investigate the primary reasons for seeking bariatric surgery and patients' expectations of surgical outcomes. The study was conducted as an international multicenter study including patients accepted for bariatric surgery from: Finland, Germany, Norway, Sweden and The Netherlands.

Paper II

The aim of this study was to explore the main reasons for seeking obesity surgery and to further investigate which items are reported by patients to be most satisfactory post-surgery in a Swedish female cohort. We also aimed to study patients' perceived satisfaction with the surgical outcome and its association to post-surgery weight loss and quality of life.

Paper III

The aim of this study was to investigate the possible change of eating behavior over time among members in a Swedish Web-based weight loss program for 6 months and secondly if there was a relationship between eating behavior and weight loss.

Paper IV

The aim of this randomized controlled trial was to evaluate if an intervention, delivered by the smartphone application PromMera, as primary outcome could increase physical activity among patients following bariatric surgery. As secondary outcome, the trial intention was to examine if the intervention resulted in an increased weight loss.

3 MATERIALS AND METHODS

3.1 PAPER I

The idea for Paper I originated in the multidisciplinary educational program European Obesity Academy. The study was designed and planned by a multinational group including members from Finland, Germany, Norway, Sweden and the Netherlands. The question put forward was “What is the main reason for patients with obesity to seek surgery?”. We were not aware of any used and validated questionnaire that could answer this question and we therefore developed, a specific questionnaire for this study.

The development of the questionnaire was done by listing various issues beyond the main reason why the participants sought surgery. Several reasons for seeking surgery as a solution to obesity were identified in the process. The reasons/items that were included in the questionnaire resulted from pre-study interviews with patients with obesity as well as physicians working with this group of patients.

The participants were also asked to estimate their own body size and how much weight they wanted to lose after surgery. Another interesting question that arose was if there were differences between included countries in terms of participants’ expectations of what would influence their weight loss most, the operation or the lifestyle changes.

The questionnaire was primarily tested for clarity. Physicians asked patients with obesity coming for an evaluation for bariatric surgery, the questions within the newly developed questionnaire to test the validity in this group of patients. This was done in all five countries before the start of the study. When we established the questions, the questionnaire was translated and validated in each of the five languages. This was done according to the European organization of research and treatment of cancer (EORTC) quality of life translation and validation protocol (91) with forward-translation from English to the native language and then backward-translation to ensure the correct content. Thereafter, a pilot study of ten patients with obesity were asked to fill in the questionnaire in each country.

In the first part of the questionnaire, general characteristics, including age, gender, co-morbidities, medication, social status, activities and education were self-reported. Weight and height were measured in the outpatient clinic and used in calculating BMI (kg/m^2). To evaluate whether the pre-surgery weight influenced the expected weight loss, calculations were made in three groups of BMI <40, 40-50 and >50 kg/m^2.

In the second part of the questionnaire, patients were asked to identify their current body shape, Perceptual Body Size, PBS, using the Stunkard silhouettes (92, 93) , see Figure 12, and to mark what they expected to look like after surgery (perceived ideal body size) using the same silhouette scale.

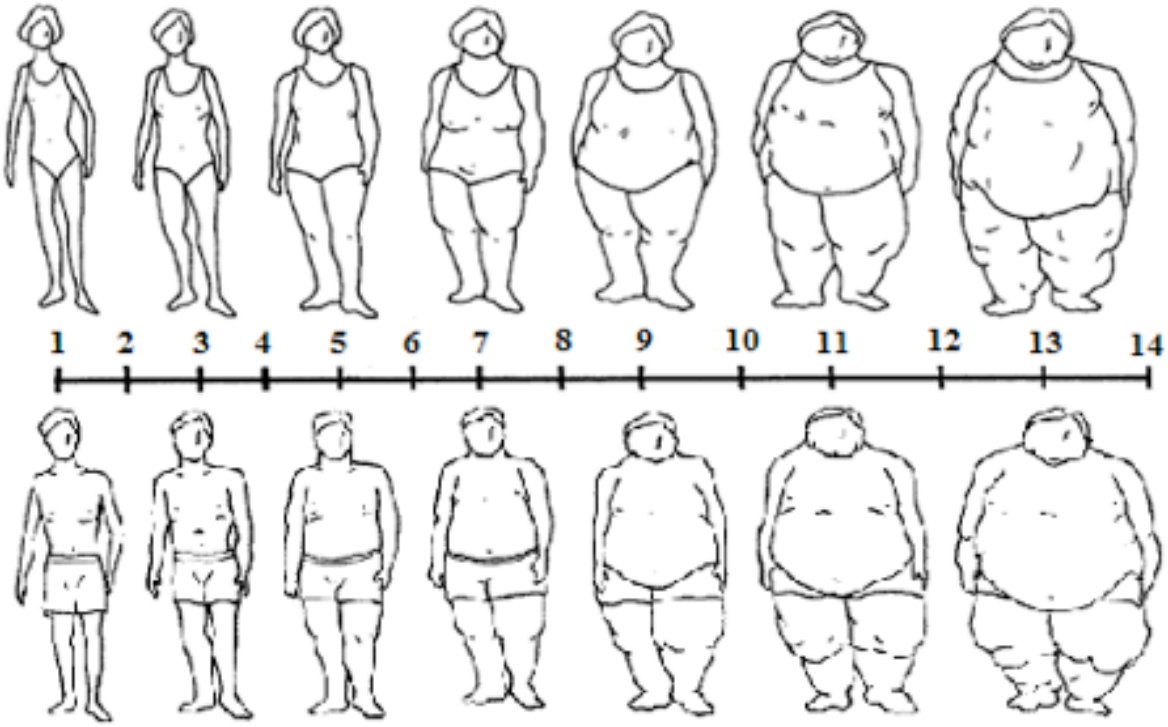


Figure 12. *The Stunkard silhouettes. Used to assess patients or study participants experienced current body size or perceived ideal body size.*

Patients were also asked how much body weight in kg they expected to lose as a result of the surgery. They were asked, on a scale from 0 to 100 %, to mark how much of the weight loss they anticipated would be due to the operation compared to lifestyle changes, see Figure 13.

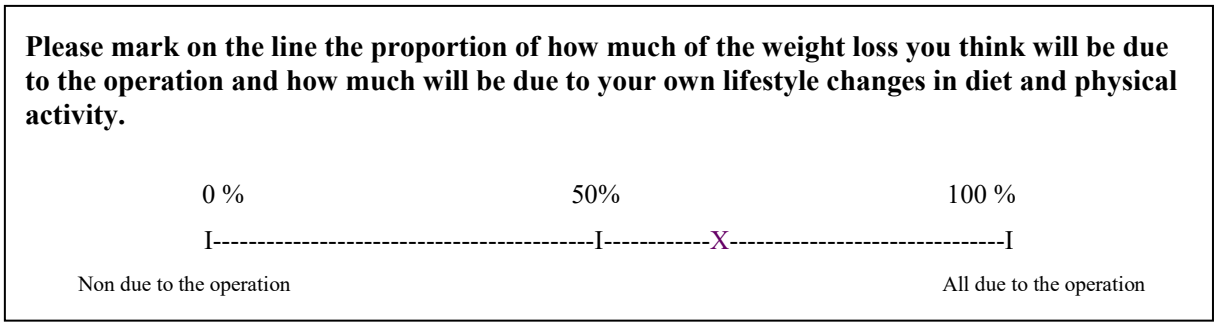


Figure 13. *To assess the participants expectations on the effect on weight loss after the surgical procedure.*

In the last part of the questionnaire, patients were asked to rank 14 different reasons to seek surgery from one (not important) to five (very important) on Likert scale. The items/reasons were: Weight loss, Taking less medication, Improvement in comorbidities, Having less pain, Chances of being employed, Improvements in social life, Expectations to live longer, Improved intimacy, Improved self-esteem, Improved fertility, Improved ability to perform sports, Having smaller clothes size, Improved psychiatric health, and Improved work performance.

Thereafter, they named the three most important reasons to seek surgery in their own words. A total score of ranking was calculated for each of the 14 reasons. In calculations, a reason listed as the most important was given ten points, a reason listed as the second most important five points, and a reason listed as the third most important scored three points.

The validated health-related quality of life questionnaire Short Form 36 (SF-36) was chosen to be included in the study questionnaire to make a 1-year post-surgery follow up of quality of life possible. The SF-36 is validated in all five countries and commonly used in studies including persons with obesity and in studies concerning outcome of bariatric surgery (58, 59, 62). So far, we have not analyzed the SF-36 data.

The study was carried out as a prospective multicenter study in Finland, Germany, Norway, Sweden and The Netherlands, including a total of 250 women, i.e. 50 women with obesity from respective country, accepted for bariatric surgery between January 2012 and January 2013. In the results the countries were categorized into two groups; the Nordic countries, including Finland, Norway and Sweden, and the Northern European countries, including Germany and the Netherlands. Categorization was due to similarities in culture and organization of public health care in the Nordic countries compared to the Northern European countries. The questionnaire was distributed to the patients at the visit for surgical evaluation before surgery (94).

Criteria for inclusion in the study were; acceptance for surgery according to International Guidelines (11) i.e. a BMI >40 kg/m^2 or a BMI >35 kg/m^2 and co-morbidity. Exclusion criteria for the study were: previous bariatric surgery or balloon, age < 18 years, or inability to read or understand the language of the questionnaire (i.e. Finish, German, Norwegian, Swedish or Dutch). Ethical permission from the Local Ethical Approval Board in each country was collected and patients gave their written informed consent for study inclusion.

The pathway for referral to bariatric surgery is different in the five countries which was challenging in planning the execution of the study. In Sweden, patients could be referred directly for surgical evaluation from the general practitioner or other physician without any evaluation by an endocrinologist. In Finland and Norway, all patients had an evaluation by an endocrinologist before referral for surgical evaluation, while in Germany and the Netherlands, patients could be referred directly for surgical evaluation from the general practitioner, or other physician but then underwent a psychiatric and endocrine evaluation and followed a diet program prior to surgery.

3.2 PAPER II

This study is a 1-year follow up of the Swedish female population included in paper I. This 1-year follow up was initially planned in all five countries included in paper I, but due to the variations in referral pathways and health care organizations, it was not possible to do so. The patients had a different time span from inclusion to surgery and a follow up was therefore not feasible in a reasonable period of time. However, since we already had developed one version of the questionnaire for baseline, one 1-year post-surgery version we decided to conduct a follow-up study in Sweden only. We thought it was interesting to study which issues the participants were most satisfied with post-surgery, if their pre-surgery expectations were fulfilled and the follow up was completed.

The cohort of Swedish women with obesity accepted for laparoscopic Roux-en-Y Gastric Bypass (RYGB) procedures at Ersta, Stockholm, Sweden, operated between January 2012 and January 2013, were invited to participate in the 1-year clinical follow up. The inclusion criterion pre-surgery was to qualify for bariatric surgery in Sweden according to the National Guidelines (11) (having a BMI >40 kg/m^2, or a BMI >35 kg/m^2 and a co-morbidity, e.g. diabetes. Informed consent was obtained from all participants prior to study start in study I.

The participants had fulfilled the study questionnaire at the surgical outpatient clinic at inclusion in study I within four weeks prior to surgery to assess baseline variables pre-surgery. The second questionnaire was sent to the participant with an invitation to a 1-year clinical follow up at the surgical outpatient clinic. As described in paper I, the questionnaire pre-surgery assessed co-morbidities, medication, marital status, children, occupation and education. This was also assessed 1-year post-surgery. Medication for hypertension, dyslipidemia, diabetes, depression and treatment for sleep apnea were assessed and answers were crosschecked with medical records. In the pre-surgery questionnaire, participants were asked to report their primary reasons for seeking surgery and their expected weight loss. Post-surgery, participants were asked the question to rate what items corresponding to the reasons to seek surgery they were most satisfied with post-surgery. They were also asked ‘Are you satisfied with your weight loss after surgery?’ and responded ‘yes’ or ‘no’ to that.

Although not the same constructs, when reporting reasons to seek surgery at baseline and items of satisfaction post-surgery, participants were asked to rank the same 14 items according to a Likert scale ranging from 1 (not important) to 5 (very important). The items were; Weight loss, Taking less medication, Improvement in comorbidities, Having less pain, Chances of being employed, Improvements in social life, Expectations to live longer, Improved intimacy, Improved self-esteem, Improved fertility, Improved ability to perform sports, Having smaller clothes size, Improved psychiatric health, and Improved work performance. Participants were also given the possibility to add free text. Finally, they were asked to rank their top three post-surgical points of satisfaction compared to the pre-surgery ranking.

As previously mentioned, the validated quality of life questionnaire, the SF-36, was used to assess general Quality of Life at baseline and post-surgery (18, 19, 56-61). The SF-36 has been used to assess health-related quality of life in patients undergoing bariatric surgery in Sweden for many years, and is included in the national quality register of bariatric surgery in Sweden, SOReg. The Short Form 36 as described earlier comprises eight domains: physical function (PF), role limitations due to physical problem (RP), bodily pain (BP), general health (GH), vitality (VT), social function (SF), role limitations due to an emotional problem (RE), and mental health (MH). The domains can be summarized into two summary scales; the physical component summary scale (PCS) and the mental component summary scale (MCS). The summary scales are calculated and standardized according to a norm-based scoring between 0 (poor health) and 100 (good health) with a mean of 50 and a standard deviation of 10.

In total, 50 women, completed the baseline questionnaire. Of these, two women did not undergo surgery and eight did not complete the post-surgery questionnaire. To assess potential reasons for not completing the study we examined the medical records of the non-responders: Reasons were psychiatric comorbidity (n=4), reoperation (n=1), other surgical procedures (n=1), emigration (n=1), and cancer diagnosis prior to the planned gastric bypass procedure leading to the procedure being cancelled (n=1). From the medical records, we were able to obtain information on body weight 1-year post-surgery for six of the eight participants who did not complete the study. Pre-surgery BMI was calculated using measured weight and height collected at the outpatient clinic, when the participants were accepted for surgery. Post-surgery BMI was calculated from weight either collected at the 1-year follow up at the outpatient clinic or self-reported weight. The patients that did not respond to the invitation to a clinical follow-

up at 1-year post-surgery or did not fill in the questionnaire was contacted with a telephone call (by me) to retrieve the self-reported weight. Some participants approved to fill in a new questionnaire sent by postal service. Change in BMI was calculated by subtracting BMI post-surgery from BMI pre-surgery.

3.3 PAPER III

This study was developed and conducted by the Karolinska Obesity Unit, Karolinska University Hospital Huddinge and the commercial web-based weight loss program at the Swedish newspaper Aftonbladet. The weight loss club was named “the Weight Club” (Swedish: Viktklubb) and was developed in collaboration with health professionals (physicians, dietitians, nurses and researchers). The program was specifically tailored to the general population in Sweden. Web-based interventions were not so common at the time for this study. The commercial web-based weight loss program offered a unique platform for recruiting participants among the registered members of the weight loss program. The participants were invited through a media advertising campaign. The challenge of this study was not to reach out to potential participants, but to keep the participants active during the whole study period.

Viktklubb.se

The weight loss club was accessible on a 24/7/365 basis for its members, see Figure 14. When becoming a member, you were asked to weigh yourself and to record and report your weight once a week. The recommended weight loss was ≤1 kg per week. Recommendations for daily energy intake were calculated using the Benedict formula (95). About 1,000 meals and recipes by well-known Swedish chefs were accessible and regularly updated. All meals were based on guidelines from the national Swedish Food Agency. The participants had the opportunity to modify or create their own recipes and use the search feature to evaluate their food choices regarding nutritional content.

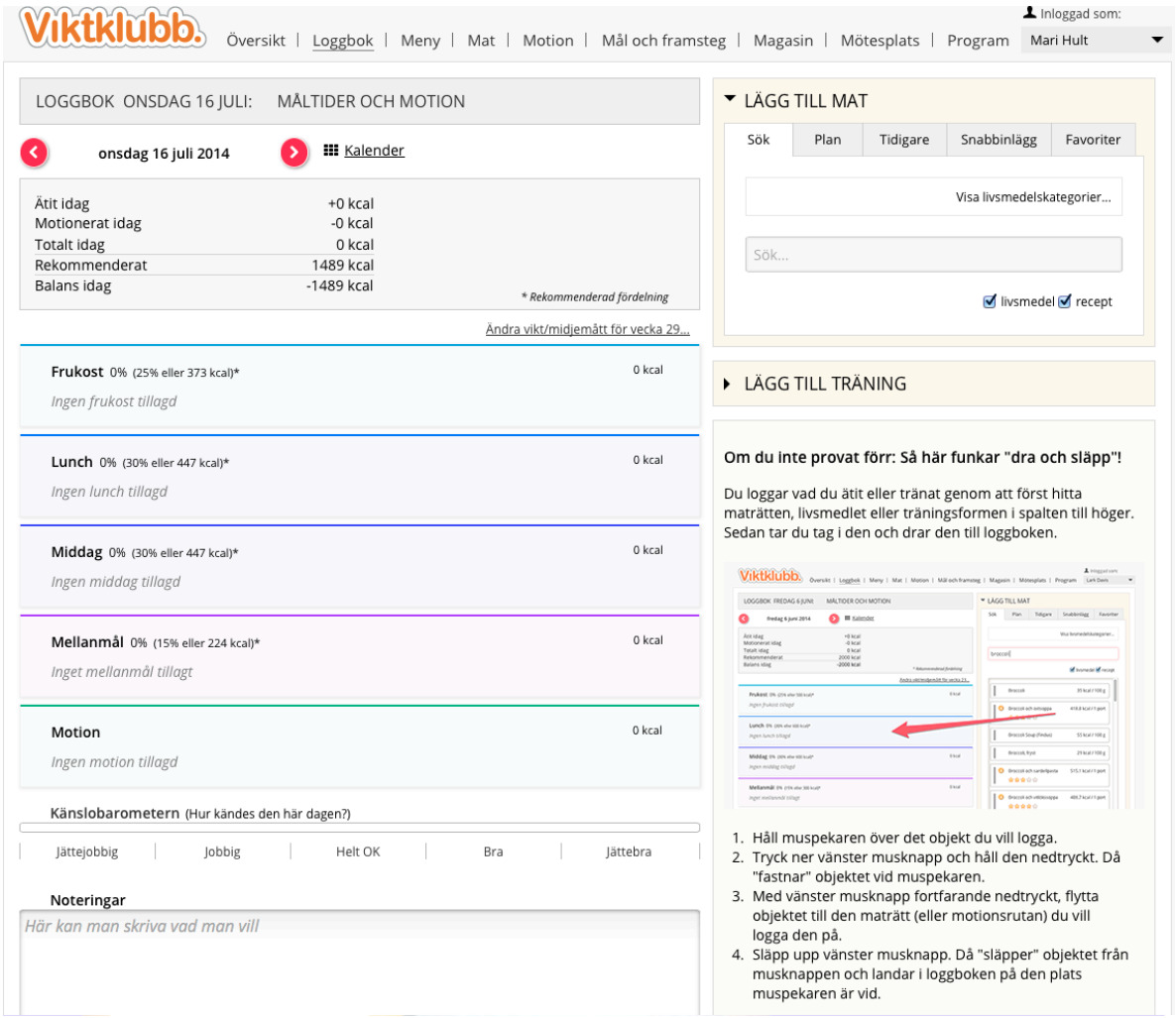


Figure 14. *Screenshot from viktklubb.se*

As a member you were instructed to frequently record your weight, food intake and level of physical activity using the online food and exercise diaries. All members automatically received feedback. This feedback was communicated to the members through the website's interactive charts and figures presenting their progress (i.e. with respect to weight loss and frequency of physical activity). E-mails with tips and advice on how to change eating behaviors to encourage weight loss and weight maintenance were sent on a regular basis. In addition, chats were available on the website allowing for exchange of knowledge, experiences, and social support during the weight loss process. The members could also use a personal blog – a feature used by 25% of the members. Additionally, members had the opportunity to participate in weekly online chats with a physician or dietician for further personal advice and support. Questions and answers from the chats were published on the newspaper's website and at the weight club's website on a weekly basis. Members who had successfully managed to lose weight were interviewed by the weight club team and these interviews were posted online.

Participants and study design

To access the weight loss program, the members had to subscribe to a 3-, 6-, or 12-month membership plan (prices ranging from €33 to €55). After subscription all members were asked to answer a questionnaire on sociodemographic and whether they were interested in participating in the study. The consenting participants were then asked to answer questions about age, weight, and height and fill out the Three-Factor-Eating-Questionnaire-Revised 18-items (TFEQ-R18), at baseline, at 3 months, and at 6 months.

The Three-Factor-Eating-Questionnaire (TFEQ) is as previously described a validated and widely used questionnaire to measure eating behaviors among heterogeneous populations (32, 34-36, 96). The TFEQ-R18 encompasses three concepts of eating behaviors including cognitive restrained eating (6 items), emotional eating (3 items), and uncontrolled eating (9 items) (31, 34, 97), see Figure 9. The TFEQ-R18 is based on scores, wherein each item question has a score. The total scores are then summed and the results are presented on a 0-100 scale, where higher values indicate a greater degree of that particular eating behavior (98).

A total of 23,233 members of viktklubb.se agreed to participate in the study. Of these, 22,844 members submitted complete information on sex, age, weight, and the TFEQ-R18 at baseline. Overall, 37 participants were excluded from the data analysis due to obviously conflicting answers (i.e. unrealistic BMI and weight goal). Also, to prevent confounding due to bariatric surgery, cancer or other issues with the potential to alter eating behaviors, 7 participants were omitted because they reported a weight loss of more than 30% in six months.

In order to study members' eating behaviors (cognitive restrained eating, uncontrolled eating and emotional eating) over time, we restricted our analyses to members who were participating continuously for six-months, as this was the most frequent time members signed up for the weight loss program. Because the weight club was open to the public (and not limited to solely study participants or patients), members entered and left the program on a voluntary basis. Hence, we only have data on those members who agreed to take part in the study and who submitted the research questionnaires.

We defined six-month compliance by restricting our analyses to participants who registered his or her weight at least once the last month and logged-on at least twice during the first three months, and twice during the second three months of participation. As a result, 4,426 participants were eligible for the study.

To study changes in eating behaviors over time we further restricted our analyses to those participants who had completed the baseline questionnaire and the TFEQ-R18, at baseline, at 3 and at 6 months, leaving 620 participants from our primary study sample. Those participants who met these two criteria 1) six-months compliance and 2) submitting complete data (baseline questionnaire and TFEQ-R18 at baseline, 3- and 6 months) were categorized as "completers". Those participants not meeting these criteria were categorized as "non-completers". See Figure 22 for a flowchart of the study.

All data were collected through the website's database and sent to the researchers on a regular basis.

3.4 PAPER IV

The research group had conducted previous studies on web-based (for example viktklubb.se) and mobile-based interventions (SMS interventions). Within my PhD research programme the idea of a randomized controlled trial in the population of bariatric surgery patients was incorporated, with the focus of physical activity using mHealth (99).

During the planning of this study there were several obstacles in the process due to the novelty of using mHealth in research. To find a designer of the application was challenging as few had adequate experience of this area.

There are many aspects to consider when including patients in an mHealth study. You have to be aware that participants are not healthy volunteers. The data has to be anonymized in the application and not traceable for others to the participants, which we secured. Secondly, where will the data be stored? In today's digital environment it is possible to store data practically anywhere in the world. There are many so called "cloud solution" to choose from. We did not want our data to leave Sweden. This proved to be a challenge, as many companies used international cloud solutions and were unwilling to see our needs. Finally, we chose a company with a cloud solution within the Swedish borders. The experience of legal questions associated with mHealth was limited at Karolinska Institutet at the time. We had ongoing discussions with KI's legal team as well as other law companies assisting Ki in this matter during all of 2016, clearly delaying the start of the study.

The design of the application also offered a number of challenges. What are the requirements of a study application? Should it be fancy and extremely technical, or maybe just simple and robust? In the end of the study, what data can one get out of the application? We were advised by the company that we could get everything we wanted, but they suggested that simple and robust might be the best solution for all participants irrespective of their experience of smartphone applications. Therefore, the only thing the participants were asked to record was their daily physical activity and their daily intake of vitamins and mineral supplements. The login was created by me for all participants. Thereby it was not traceable to the individual person without the code book.

In November 2019 we had a serious setback when the last randomized participant contacted us as the application was not possible to download and start. The company that had programmed and run the application had closed down in the summer 2019, but no one from the company informed us about this. The lesson learned is that many of the app companies are backed by venture capital. If the company is not profitable it goes down. To prevent that a research study like ours fail due to this, a more comprehensive contract is needed.

In the end, the PromMera application was saved by earlier employees at the company, enabling us to get the last participants through the intervention and save our data from the application platform.

Another unexpected problem throughout the study was loss of questionnaires and accelerometers in the postal service. The participants were contacted when questionnaires and accelerometers were not returned and many then responded that they already posted it.

The study started to include patients referred for bariatric surgery to the surgical outpatient clinic at Vrinnevi Hospital in November 2017. the inclusion ended May 2019. All patients fulfilled the indication for surgery (i.e. BMI ≥35 kg/m^2 and an obesity related co-morbidity or BMI ≥40 kg/m^2). According to the local routine, the patients were invited for a group information meeting where they were informed about the surgical procedure, as well as given oral and written information about the study (99).

The patients received the team's decision of acceptance for surgery by a call from a nurse. During this telephone call they were then again given oral information about the PromMera study. Those who agreed to participate in the study gave their oral consent during the call. Written informed consent was also collected from each participant. The inclusion criteria were: accepted for bariatric surgery at Vrinnevi Hospital, between 18 and 60 years, ability to read and understand Swedish, and access and ability to handle a smartphone. Exclusion criteria were: disability preventing daily walking.

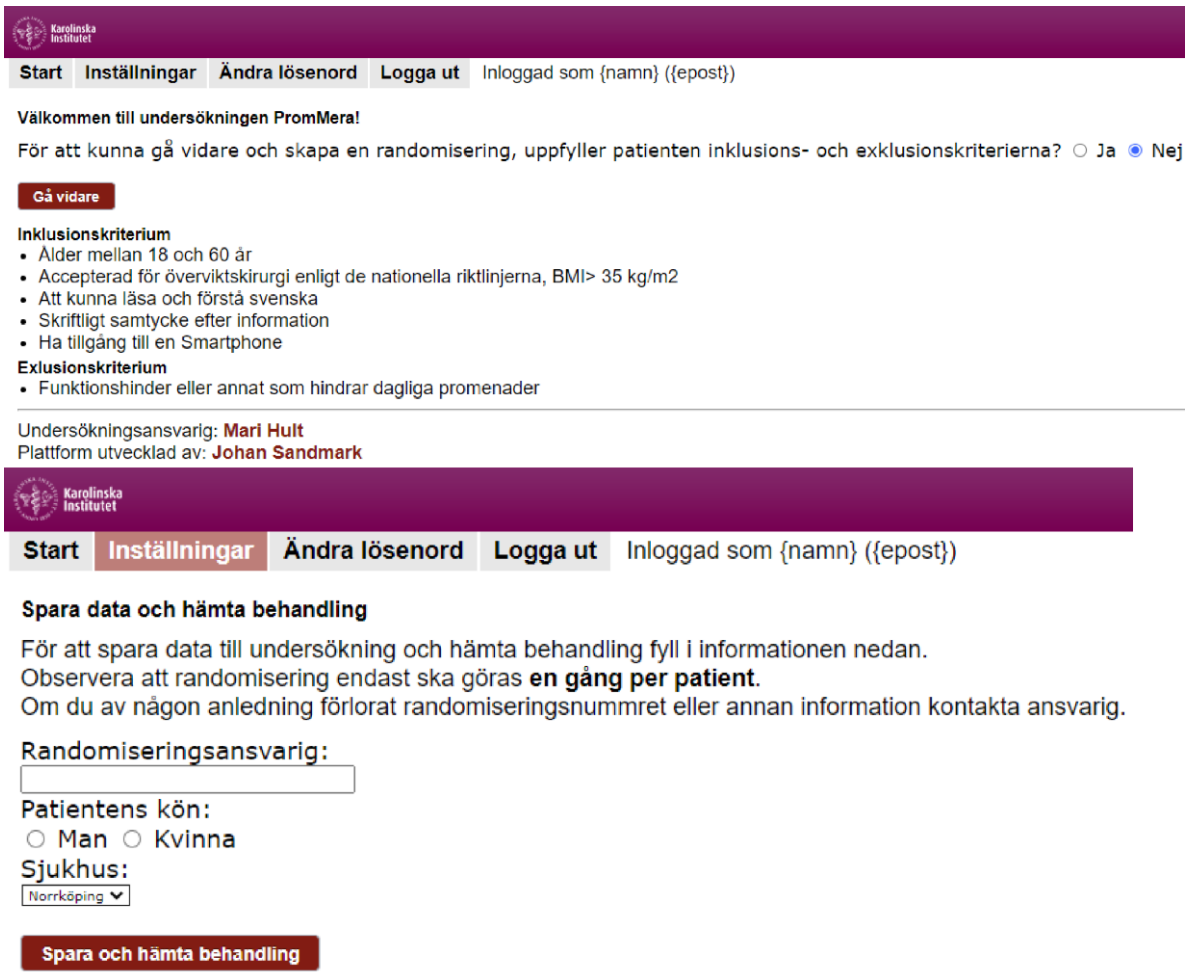


Figure 15. *The program (prommerastudie.se) used to randomize in the PromMera study.*

The participants were randomly allocated to the intervention or control group through an online randomization program (prommerastudie.se), see Figure 15. We used block randomization due to the large gender difference among bariatric surgery patients, where women are in majority. Women were randomized in blocks of 4, and men in blocks of 2. The participants were randomized the day after their surgical procedure and were informed about their allocation at the 6-weeks post-surgery appointment, see Figure 19. There was no difference in routine information or post-surgery care between the groups. We were not able to blind the groups though the application itself was part of the intervention, but one could argue that an application without possibility to record and no push-messages to the control group would have been a way of blinding.

mHealth intervention

Those randomized to the intervention group were given their personal, but anonymized login to the PromMera application at the 6-weeks post-surgery appointment. They were thereafter able to use the application during the following 12-weeks, see Figure 16, for screen shots.

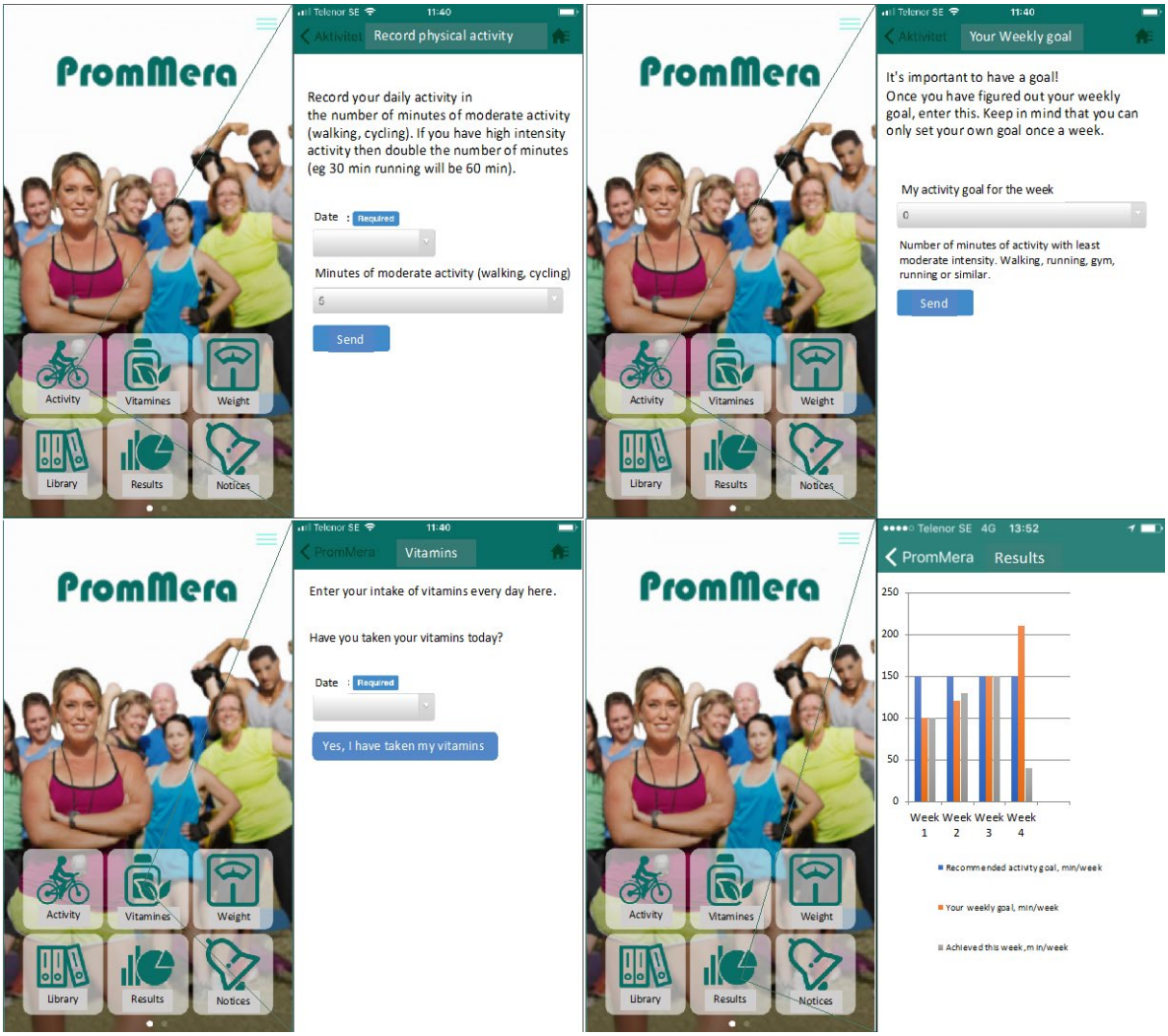


Figure 16. *Screenshots from the app PromMera*

Every Monday, the participant got a notification to set a weekly goal for total minutes of physical activity. Selectable options were: 100, 150, 210 and 250 minutes. The participants were informed about the recommendation by WHO of 150 minutes physical activity per week of at least moderate intensity. They were however encouraged to set a daily goal of 30 minutes, i.e. 210 minutes per week, to improve their health and weight loss even more. They were asked to record all minutes of performed physical activities of moderate to vigorous intensity daily. They could record their activities in bouts of 5 minutes, from 5 to 60 minutes, and in bouts of

10 minutes, from 60 to 210 minutes. If the performed activity was vigorous, they were instructed to double the number of minutes. It was possible to record activity conducted previous days, as well as several bouts of activity each day. A daily reminder to record activity was sent to participants at 8 pm.

A graph illustrated the individual goal and total minutes reported per week, see Figure 16. On Sundays the participants who reached their personal goal and/or had recorded at least 150 minutes of physical activity, received a message of encouragement to keep up the good work during the upcoming week. Those who did not reach the goal, got a message with encouragement to try again next week.

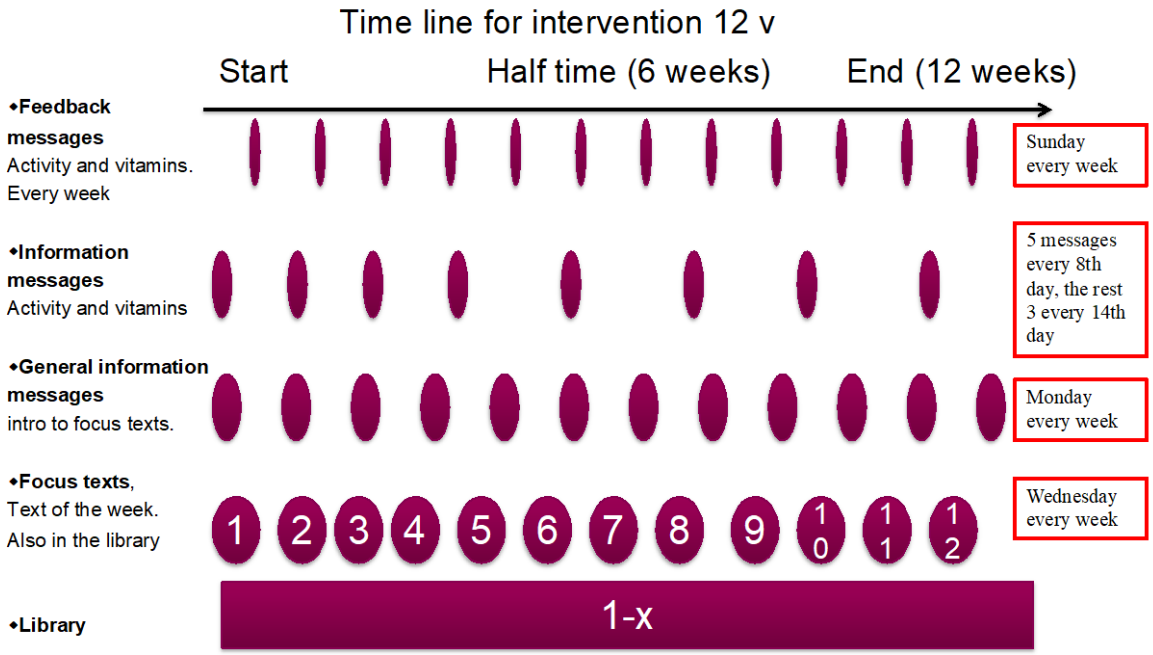


Figure 17. *The schedule for texts sent as push-messages within the PromMera app.*

The participants could also record weight once a week. They could find information regarding physical activity, medications after surgery, vitamin supplementation and diet recommendations in a library included in the application. In a pre-determined schedule, the participants received push-messages with information and encouraging texts, see Figure 17. The frequency of short information messages was higher in the beginning of the intervention period, every 8th day, and less frequent towards the end, every 14th day. The longer texts were sent out with the heading as a push notice on Mondays and Wednesdays weekly during the 12-

week intervention period. Each week of the intervention came with a specified theme, for example how to start exercising, diet recommendations for the early post-operative period, medical issues etc. The intervention strategies within the application were based on social cognitive theory and behaviour change theories from Michie's taxonomy (100, 101). In the app, the participants could also find contact information to clinical staff at Vrinnevi hospital, and to those responsible for the study.

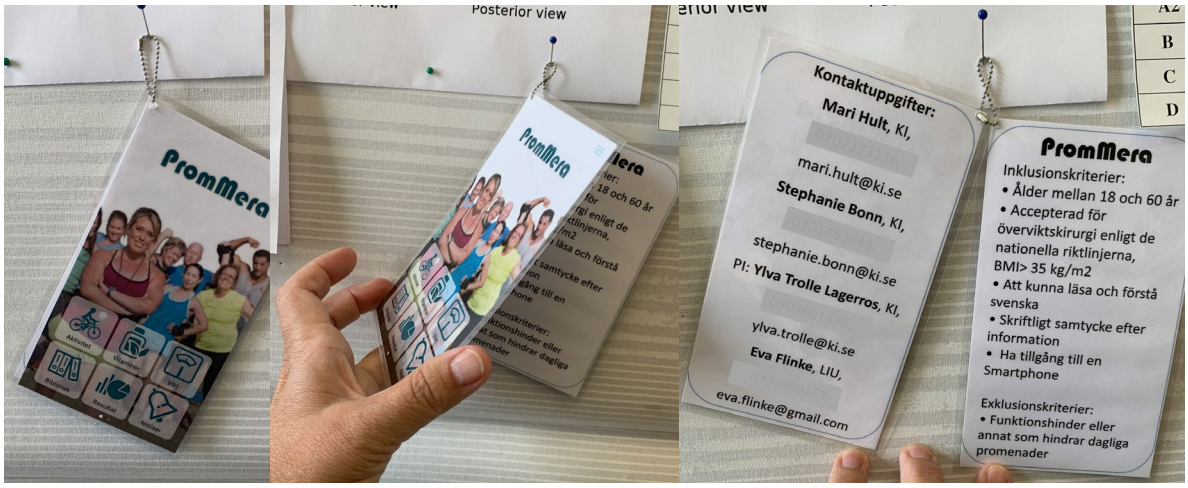


Figure 18. *Badges to remind the study personnel of the inclusion and exclusion criteria in the PromMera study*

Measurements

A flow-chart of the study design is illustrated in Figure 19. A questionnaire assessing basic characteristics like medical history, education and marital status was sent together with an accelerometer to the participants via mail at baseline. The questionnaire and the accelerometer were returned to the researchers in a pre-paid and addressed envelope. If the mail service failed, another set of questionnaire and accelerometer was sent to the participants. At 18-weeks post-surgery, an accelerometer and questionnaire were sent to the participants again with a pre-paid return envelope.

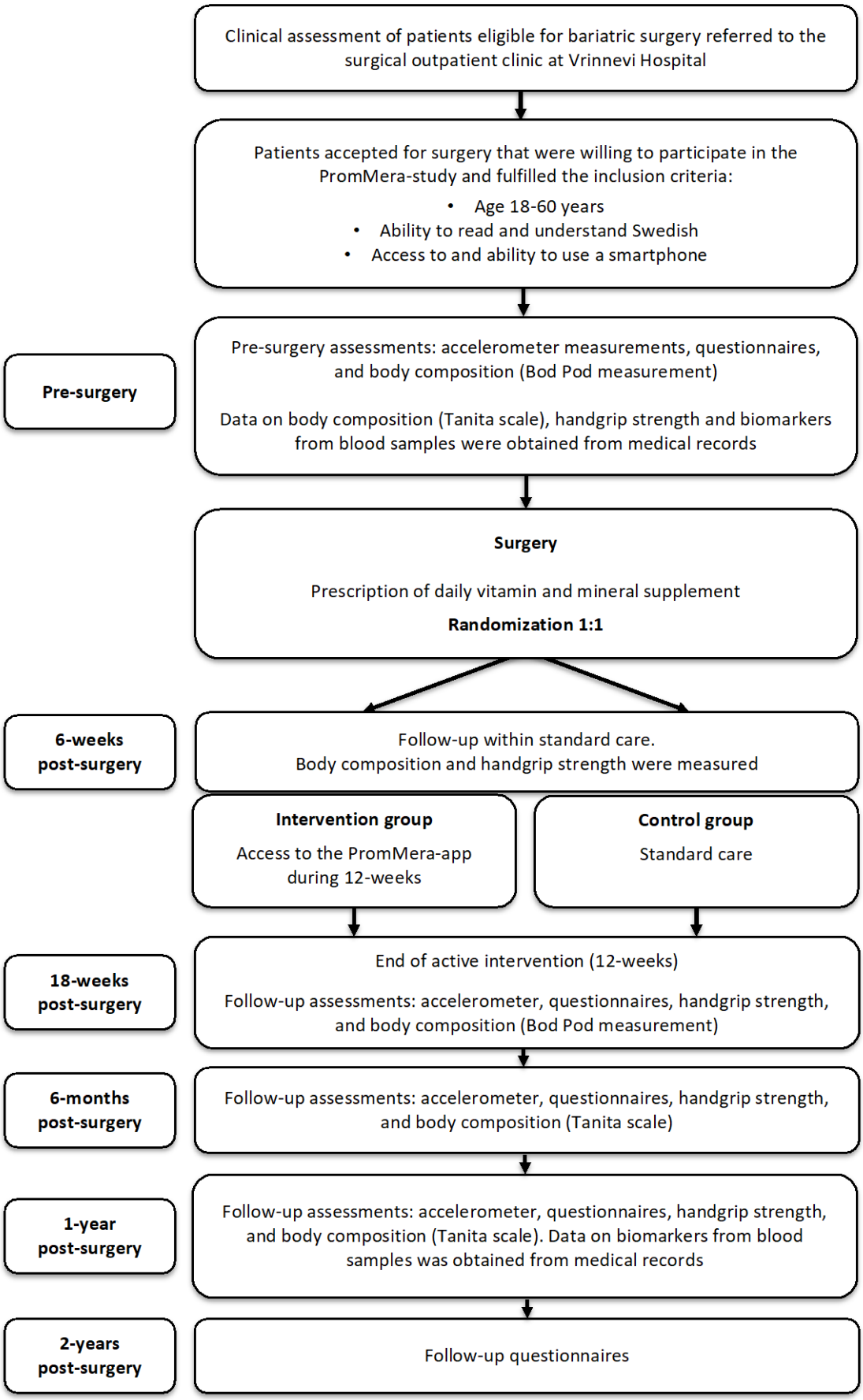


Figure 19. *Flowchart of the PromMera study*

Anthropometric measurements

At baseline and 6-weeks post-surgery, weight was measured with a Tanita body composition scale with light clothing and without shoes. At baseline and 18-weeks post-surgery, 94% of the participants were measured with BodPod®, air displacement plethysmograph, wearing light close-fitting clothes only. Those unable to perform measurement in the BodPod® were measured with the Tanita scale, while participants who could not physically come to the clinic, self-reported their weight. Height was measured at baseline at the surgical outpatient clinic. Body Mass Index (BMI) was calculated as weight in kilograms divided by squared height in metres. In Table 2, all questionnaires included in the PromMera study are listed.

Table 2. *The questionnaires included in the PromMera study*

Questionnaire	Assessing	Assessed at
Three Factor Eating Questionnaire-Revised 21(TFEQ-R21)	Eating behavior	Baseline, 18-weeks, 6-months, 1-and 2-years post-surgery
Short Form 36 (SF36)	Health related Quality of Life	Baseline, 18-weeks, 6-months, 1-and 2-years post-surgery
Karolinska Sleep questionnaire	Sleeping habits	Baseline, 18-weeks, 6-months, 1-and 2-years post-surgery
Neighborhood Environment Scale	Neighborhood environment accessibility, social environment, and safety	Baseline, 18-weeks, 6-months, 1-and 2-years post-surgery
International Consultation on Incontinence Questionnaire	Symptoms related to urinary incontinence or prolapse	Baseline, 18-weeks, 6-months, 1-and 2-years post-surgery
Food Frequency Questionnaire (FFQ)	Dietary intake comprising food items and beverages, including alcohol	Baseline, 6-months, 1-and 2-years post-surgery
National Board of Health and Welfare's general questions about physical activity and sedentary activity	Time spent on physical activity or sedentary activity	Baseline, 18-weeks, 6-months, 1-and 2-years post-surgery
App evaluation questionnaire	Experience of the PromMera app	18-weeks post-surgery, intervention group
Medication Adherence Report Scale (MARS)	Adherence rate for vitamin and mineral supplement	18-weeks, 1-and 2-years post-surgery
Beliefs about Medicines Questionnaire Specific (BMQ Specific)	Attitudes towards vitamin and mineral supplement	18-weeks, 1-and 2-years post-surgery

Physical activity

Physical activity was measured using the triaxial Actigraph wGT3x-BT accelerometer (Actigraph Corporation, http://actigraphcorp.com) (102). The participants were asked to wear the accelerometer on their wrist during all hours for seven consecutive days, at baseline and 18-weeks post-surgery. The participants were instructed to record all non-wear time in a diary, e.g. when performing water activities or removing the accelerometer for other reasons.

The accelerometer collected data at 80 Hz. Raw acceleration data were extracted through ActiLife version 6.13.3 and processed using open source R-package GGIR version 2.0-0 (https://cran.r-project.org/web/packages/GGIR/index.html). Data was aggregated through application of Euclidian norm minus one (ENMO), where negative values were rounded up to zero. Default settings were applied, which among other things included: averaging data over five second epochs, autocalibration using local gravity and replacing non-wear time with imputed data from the same time period in the other measurement days (103-105). All participants with available GGIR part 5-data, at least 14 hours wear time, from at least four days of which at least one day during the weekend, were included in the analysis. MVPA was calculated using GGIR default cut point for non-dominant wrist (100 mg) (106). Further, the MVPA-variable was weighted to consist of 5 parts of data collected during the weekdays, and 2 parts during the weekend. Similar to the Whitehall II study (107), MVPA was measured in bouts of at least 1 minute, where 80 % of the epochs had to be above the MVPA-threshold (but only epochs above the threshold were classified as MVPA).

Application data

From the web-based platform for the smartphone application we were able to retrieve the number of occasions that the participants recorded their physical activity, the number of minutes they recorded, their weekly goal and if recorded their weekly weight. The registered activity from the application was summarized as moderate physical activity (MPA). Vigorous activity was registered as double number of minutes of moderate activity.

3.5 STATISTICAL ANALYSIS

Characteristics of study participants are presented as numbers (n) and percentages (%) as well as mean values, range (Min-Max) and standard deviation (SD) in all included studies. P-values <0.05 were considered statistically significant.

An overview of the statistical analyze methods and software programs used for the statistical analysis are presented in table 3.

Table 3. *Statistical methods and software programs utilized in each study.*

	Paper I	Paper II	Paper III	Paper IV
Descriptive statistics	x	x	x	x
Kruskal-Wallis test	x			
Fischers exact test	x			
Mann-Whitney U test	x	x	x	
Independent t-test				x
Paired t-test				x
Chi^2 test				x
Pearson's Chi square test			x	
Ordinal logistic regression	x			
Repeated measure analysis of variance (ANOVA)			x	
Pearson's correlation			x	
Analysis of covariance (ANCOVA)				x
Wilcoxon signed-rank test				x
Software programs				
STATA 14.2 (StataCorp LP, College Station, Texas)	x			x
SAS version 9.4		x		
SPSS 15.0 for Windows (SPSS Inc)			x	

For continuous variables, the Kruskal-Wallis, Mann-Whitney U or Independent t-test were used to test differences between groups. The Fischer's exact test and Chi^2 test were used to test differences between groups in categorical variables. For non-normal distributed and non-parametric categorical variables, the Mann-Whitney-U test was used in Paper II. In Paper III, the Pearson's Chi Square test was used to test for differences in the categorical variable (level of education) between completers and non-completers.

To assess odds ratios (OR) with 95% confidence intervals (CI) in Paper I in order to compare the importance of reasons reported by different categories of patient's, ordinal logistic regression was used. A repeated measure analysis of variance (ANOVA) was used to analyze the change in eating behavior over time and potential differences between genders in Paper III. In the same paper, Pearson's correlation coefficient "r" was used to analyze the relationship between change in eating behavior and the total weight loss percentage over 6-months.

To compare the intervention group and control group in Paper IV regarding moderate-to-vigorous physical activity and BMI at the 18-week follow-up, analysis of covariance (ANCOVA) was used. Paired t-test was used to compare accelerometer-measured moderate-to-vigorous physical activity within each group. To analyze if the completers reached the weekly goal of 150 respectively 210 minutes/week of moderate-to-vigorous physical activity the Wilcoxon signed-rank test was used.

3.6 ETHICS

Ethical considerations of the included papers

There is a proven/well known controversy in treating people for obesity that can be discussed from an ethical perspective. Do you not have the right to be obese without experience stigma from the environment and healthcare? Is it fair to be subjected to comments on what you eat or whether you exercise enough? With respect for a person's autonomy, a person with obesity has the right to live their life with obesity even if it is known that obesity may lead to morbidity and mortality. Several activities are potentially harmful; smoking, alcohol abuse, mountain climbing, horseback riding, boxing and does not lead to the same stigmatizing as obesity.

But as there is a scientifically established causal link between obesity and other diseases, such as diabetes, high blood pressure, cardiovascular disease and even cancer, health professionals see it as their duty to work for weight reduction in patients with obesity. This according to the principle of beneficence or "doing good". But patients' own wishes must also be respected when, in accordance with their negative right, they refuse further treatment or decline offered surgery.

The general experience of many patients is rather that they have to fight for their positive right to have surgery and struggle with long queues within the health care system or other obstacles along the way. They are more often in a role of dependent to the health care professionals whereas it is hard to, for example, say no to participate in a research study.

Paper I:

Ethical approval from the Regional Ethical Review Board in Stockholm was obtained:

Dnr: 2012 / 302-31 / 1

Within the health care system, bariatric surgery is considered beneficence for patients with obesity, surgery can reduce their pre-existing morbidity or prevent sequelae of obesity. In clinical everyday life, however, other perspectives from the patients are encountered but we do not know whether these correlate to any acquired co-morbidities, age or perceived stigma etc. The information given to patients is mostly the same regardless of age, gender and co-

morbidity. According to the “principle of fairness” or justice in the aspect of access and participation, you can argue that all patients, regardless of the disease they suffer from, have the right to personalized information. This study may contribute to more individualized information pre- and post-surgery.

To reduce the risk of imposing patients to say yes to participation in the study, the research nurses gave detailed information about the aim of the study and the right to decline inclusion. From the perspective “no harm principle” or non-maleficence, this survey may have infringed privacy to a certain degree both regarding issues that are very personal, such as "how do you rate intimate contact as a reason for surgery" as registering personal data. If you consider that the collected information is deidentified in the analysis and therefore not traceable to a person, the infringement of privacy can be considered negligible. The patients sign an informed consent and participation in the study is voluntarily. The participants were also able to end their participation in the study at any time. The time that was required to complete the questionnaires was a sacrifice on the part of the participants but was of service for research and hopefully for the benefit of future patients.

In the “doing good” aspect, it is difficult to see a direct benefit for the study participants, but it may have given them a deeper reflection up on their choice to undergo surgery.

Paper II:

Ethical approval from the Regional Ethical Review Board in Stockholm was obtained:

Dnr: 2012 / 302-31 / 1

In the 1-year follow-up of the Swedish cohort in paper I, where the participants were asked about their satisfaction with the outcome of the operation, i.e. the weight loss, and what item they most appreciated after the operation. A questionnaire was sent out before their routine 1-year follow-up visit at the outpatient clinic. The same ethical considerations as in paper I can be applied here. A follow-up with the study questionnaire at the routine 1-year follow-up after surgery can provide the patient with an opportunity to reflect on how the expectations were met or not and can give a deeper insight into pros and cons.

Paper III:

Ethical approval from the Regional Ethical Review Board in Stockholm was obtained:

Dnr: 2003/85: 03

The purpose of the study was to see if a Web-based weight loss program could provide an alternative to similar programs in general healthcare. Traditional programs are relatively expensive as they require a certain staff density and also that the patient is present in person. eHealth could theoretically improve the access, equity and participation (justice) for the patient. The study group also wished to investigate whether there were other parameters that could affect changes in eating behavior and weight loss such as age, gender, level of education, etc. If such differences could be demonstrated, the benefit for the individual patient could be amplified. Then future weight loss programs could be designed in consideration of individual differences. In addition, the programs can be more cost-effective, which would be benefit the health economy. This knowledge could also be applied to patients with obesity or overweight as far as other lifestyle changes are considered.

The participation in the study was voluntary and the participants were able to end their participation at any time. If they dropped out of the study, their data would not be used in the analysis. The ethical issue in this study mainly concerns a possible perceived infringe of privacy, but this must be regarded as negligible and the participants have the right to leave the study at any time. The uncertainty in how data is handled within the study, i.e. whether personal data is disclosed, could affect the participants. The confidentiality was protected by the deidentifying of data and handling in accordance with PUL, the Personal Data Act.

Paper IV:

Ethical approval from the Regional Ethical Review Board in Stockholm was obtained:

Dnr: 2016 / 1259-31 / 4, 4-2005 / 2017, 2017 / 2101-32

We are ethically obliged to compare new methods with the current before we change the praxis. A randomized control trial is golden standard to conduct if possible.

When the participants gave their informed consent to this study, the intention was that they were well informed about the need for lifestyle changes in connection with the operation, so that they based on their autonomy, could decide about their participation in the study.

In this study, we require a non-neglectable amount of time from the participants. A large questionnaire and an accelerometer were sent out at five occasions. The time required for filling in questionnaires and wearing the accelerometer can be experienced as stressful but also be motivating for the required lifestyle change.

The accelerometer measurement of physical activity for one week including nighttime could have been perceived as a practical inconvenience, but not harmful. Some patients experienced the measurement of body composition that took place in Linköping as a problem due to the distance from home and the work leave. Most participants did though express appreciation and mentioned that the BodPod® measurement was a positive feedback on their weight loss after surgery. Some patients did not tolerate the examination due to claustrophobia.

The hypothesis was that the participants in the intervention group would experience the app as a motivator to increase their degree of physical activity and thus in the long term improve their results regarding weight. In that sense the app would "do good" and hopefully lead to reduced morbidity and better quality of life etc.

If we assume that increased physical activity can improve outcome after surgery, why were not all patients offered the opportunity to use the app? As discussed before, randomized control trials like this is needed to prove a difference due to the intervention and therefore a control group is required. A sham app for the control group would have been an alternative but was not an option in this study. To ensure the participants privacy their login to the app was not linked to them personally.

If a positive difference in physical activity associated to the intervention is proven there is the possibility to introduce the app in the standard care. A study like this will also evince if the

participants become too stressed by daily remarks about exercising and therefore unsuitable for standard care. The benefit must be demonstrated before it can be included as a standard in care, the development and maintenance of a smartphone app is also a cost to society. If the app intervention shows positive results, it can be a cost-effective supplement in the care of persons with obesity.

4 RESULTS

4.1 PAPER I

The mean age of the 250 women was 42.9 (11) years, mean weight was 125.9 (20) kg, and mean BMI was 45.1 (6) kg/m^2. There were differences in BMI, weight, level of education, co-morbidities and marital status between the countries. In the Northern European countries (Germany and the Netherlands) the patients had higher BMI compared to patients in the Nordic countries (Finland, Norway and Sweden), 47 kg/m^2 and 44 kg/m^2 respectively ($p<0.001$). In the Nordic countries, the number of participants with a university degree was higher compared to the Northern European countries, 22% and 8% respectively ($p<0.007$).

The three most important reasons for seeking bariatric surgery, rated by the participants, were weight loss, improved co-morbidities and longevity. There were differences between countries, in Finland and Germany, improved co-morbidities were rated as the most important reason. In Norway, Sweden and the Netherlands, weight loss was the most important reason to seek bariatric surgery.

The expected weight loss after surgery was on average 42 kg, which was almost 80% of their excessive weight. Those with a lower BMI, less than 40 kg/m^2, expected to lose more of their excessive weight than the group with a BMI more than 50 kg/m^2 ($p<0.0001$).

The odds ratio for rating the most important reason in the different categories of study participants presented several significant differences. The category with co-morbidities rated less medication and reduced co-morbidity as more important than the category without co-morbidities, OR: 7.55, 95% CI: (4.25-13.42) respectively 3.99, 95% CI: (2.14-7.46). The OR for participants with insulin treatment to rate less medication and reduced co-morbidities as more important than those without insulin treatment were higher, OR: 7.02, 95% CI: (2.94-16.75) respectively 5.18, 95% CI: (1.87-14.40). The participants with children rated less medication, longevity and improved self-esteem higher than those without children, OR: 2.53, 95% CI: (1.49-4.31), 2.30, 95% CI: (1.23-4.30) and 2.05, 95% CI: (1.19-3.52). The categories unemployed or on sick leave, rated increased chances of employment higher than the category with employment, OR: 8.10, 095% CI: (3.98-16.49). The category of participants with a BMI

less than 40 kg/m^2 or more than 50 kg/m^2 presented no differences in rating their most important reason to seek bariatric surgery.

In total, the participants expected that 68% of their post-surgery weight loss would be an effect of the operation alone and 32% of the weight loss would be due to their lifestyle changes. Participants from the Northern European countries had higher expectations on the surgical effect on their weight loss, 83%, compared to the Nordic countries, 58%, ($p<0.0001$), see Figure 20.

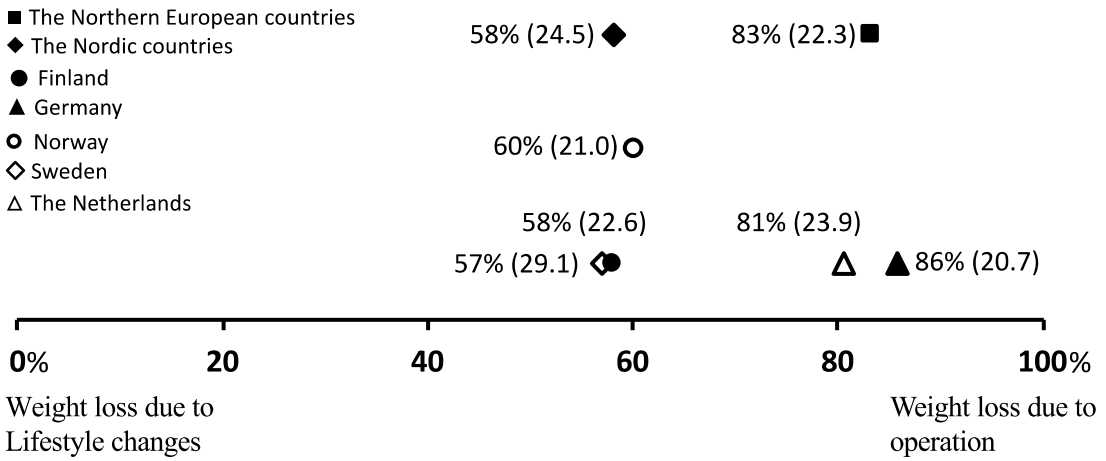


Figure 20. *Participants were asked to make a mark on a scale from 0 to 100 (10 cm) whether the expected post-surgery weight loss would be due to only lifestyle changes (0%) or only operation (100%).*

The pre-surgery body image marked on the Stunkard silhouettes were pre-surgery 9.2 (2.1) and the expected post-surgery body image was 5.8 (5.8) on the same scale.

4.2 PAPER II

Forty of the fifty Swedish women who completed the questionnaire before surgery in Paper I did also complete the post-surgery assessment. Body Mass Index was 40.9 (5.2) kg/m^2 pre-surgery and 27.8 (5.3) kg/m^2 post-surgery. That results in a change in BMI of -12.9 (3.7) kg/m^2 comparing pre- and post-surgery. The most common co-morbidities reported before surgery was musculoskeletal pain and/or arthrosis, 52%, and psychiatric disorders, 40%. At the follow-up 1-year after surgery they were decreased to 18 and 22%, respectively. Only one participant in the Swedish cohort had insulin treatment.

Before surgery the main reason to seek surgery was weight loss, the second most important reason was reduced co-morbidity and the third most important was longevity, see Table 4. The three items of most satisfaction 1-year after surgery was improved self-esteem, weight loss and longevity.

Table 4. *The top three most important reasons to seek a surgical solution for obesity and the top three items of most satisfaction 1-year after surgery.*

Top three reasons to seek surgery		Top three items of satisfaction post-surgery	
Weight loss	47.9%	Improved self-esteem	55.6%
Reduced co-morbidity	41.7%	Weight loss	41.7%
Longevity	35.4%	Longevity	38.9%

The participants who expressed satisfaction with their weight loss 1-year after surgery had a mean change in BMI of -13.4(3.6) kg/m^2 compared to those who were unsatisfied, -11.0 (4.1) kg/m^2 (p=0.06). For the satisfied participants, that weight loss corresponded to a mean %Excessive Weight Loss (%EWL) of 94.6(22.9). Whereas the unsatisfied participants had a mean %EWL of 59.9(17.6) (p=0.002). All participants with an %EWL over 80 were satisfied with their weight loss after surgery.

In SF-36, the Mental Component Score were improved for 32 participants (86.5%) and in General Health 35 participants (94.6%) scored higher at the 1-year follow-up after surgery. As you can see in Figure 21 there was improvement in all domains at 1-year post-surhgery. Participants' satisfaction had no significant association to either Mental Component Score or Physical Component Score 1-year after surgery.

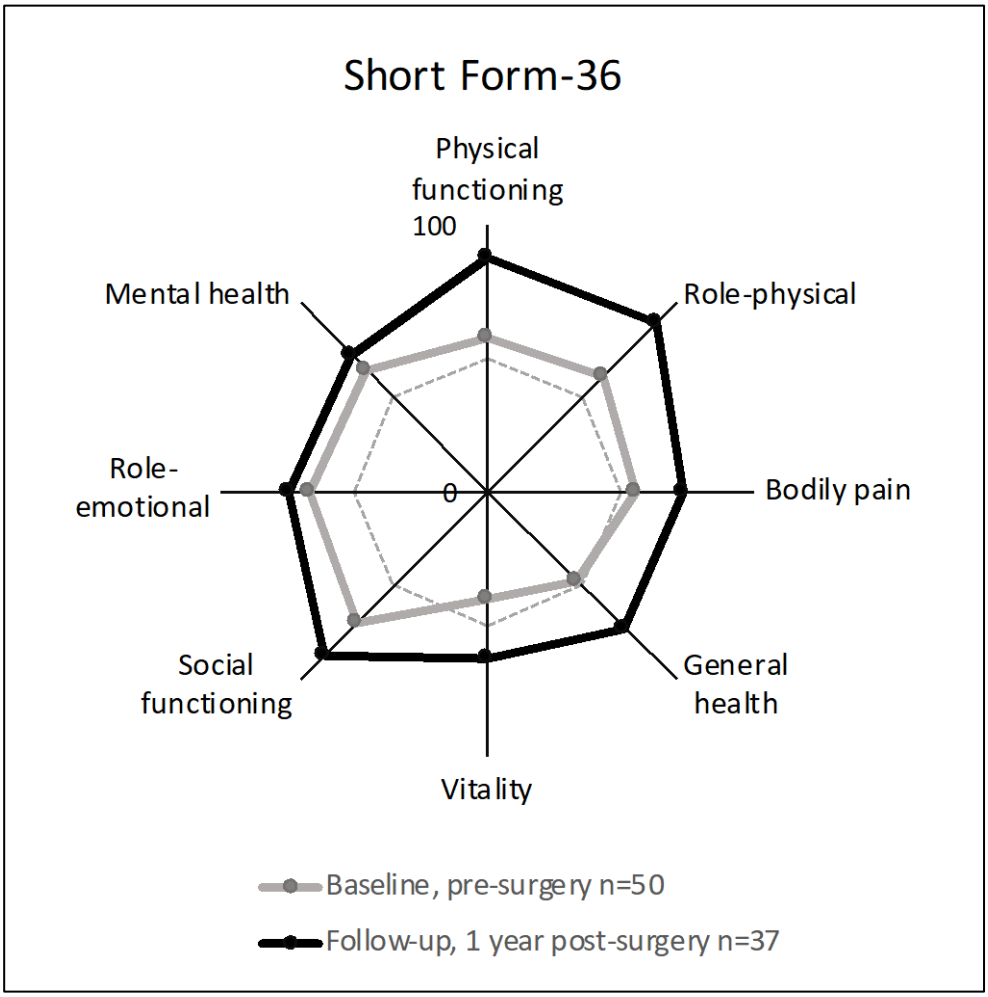


Figure 21. *SF-36, health related quality of life: The pre-surgery and 1-year post-surgery, differences of the eight domains, (n=50) respectively (n=37).*

4.3 PAPER III

The mean BMI at baseline was 29.0 (5.0) kg/m^2 for the 19,065 (83.6%) females and 30.8(4.3) kg/m^2 for males.

The differences between completers and non-completers at baseline were age, education and BMI. Both male and female completers were older than non-completers ($p<0.001$ and $p=0.002$). The female completers had higher education and higher BMI than female non-completers ($p=0.02$ and $p<0.001$).

The average weight loss at 6 months was for female completers 5.8% (5.0) and male completers 7.0% (5.1).

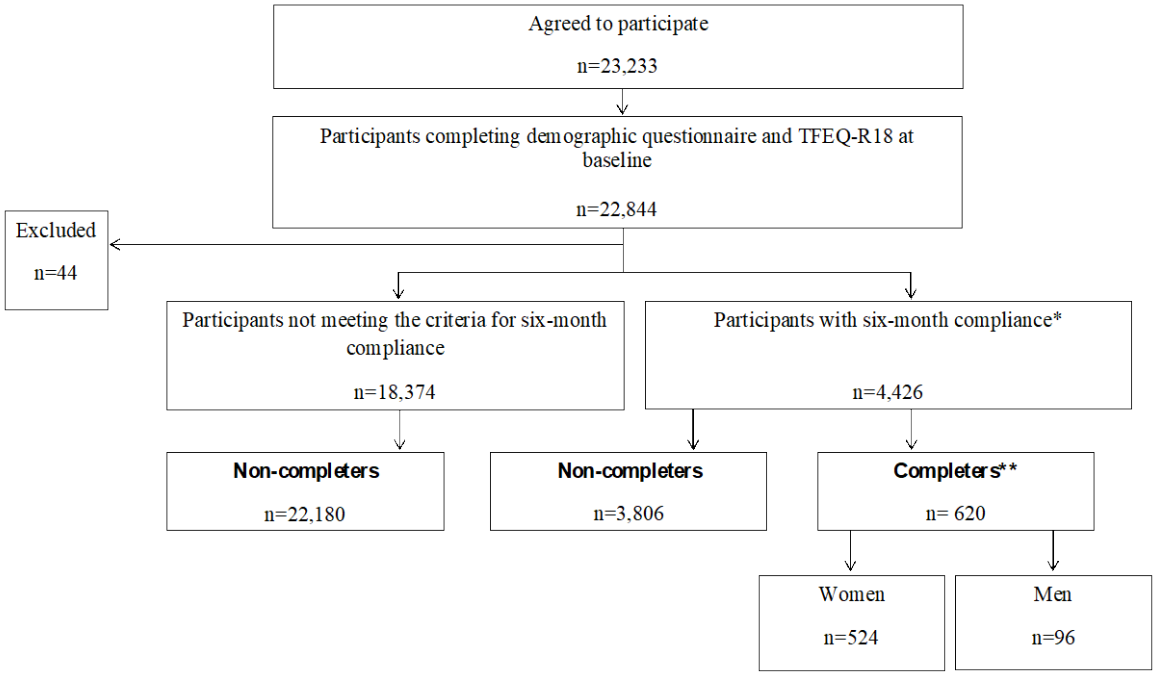


Figure 22. *Flowchart of study III. *Six-month compliance was defined as follows: a participant who registered his or her weight at least once the last month and logged-on at least twice during the first three months, and twice during the second three months of participation. **Completer was defined as follows: a participant completing the TFEQ-R18 at baseline, 3- and 6 months of participation.*

Table 5. *Eating behavior at baseline*

Eating behavior, mean (SD)	Women				Men			
	All n=19,065	Completers n=524	Non-completers n=18,541	p-value*	All n=3735	Completers n=96	Non-completers n=3639	p-value*
Uncontrolled Eating	51.8(15.1)	56.8 (13.6)	51.6 (15.1)	**<0.001**	51.7 (14.8)	56.8(13.6)	51.5(14.8)	**0.001**
Emotional Eating	43.5(30.3)	57.2 (28.4)	43.5 (30.4)	0.14	55.3(28.9)	57.2(28.4)	55.3(28.9)	0.57
Cognitive Restrained Eating	48.6(11.4)	50.8 (10.9)	48.5 (11.4)	**0.002**	47.2 (12.2)	50.8(10.9)	47.1(12.2)	0.09

*p-value based on Mann-Whitney U test, p-values <0.05 were considered statistically significant

Differences in eating behavior between completers and non-completers at baseline are presented in Table 5. There were significant differences for both genders in uncontrolled eating, were completers reported higher scores than non-completers (women: $p<0.001$, men: $p=0.001$). In cognitive restrained eating, female completers reported higher scores than female non-completers ($p=0.002$). Baseline cognitive restrained eating score was associated with weight loss among completers (women: $p=0.020$, men: $p=0.002$).

Repeated measure analysis of variance (ANOVA) to investigate any change in eating behavior over time and potential differences between genders was done. The uncontrolled eating score was significantly decreased over time for both men and women ($p<0.001$). Contrary to that, the cognitive restrained eating increased for both genders over time ($p<0.001$). For emotional eating, an interaction between time and gender was seen ($p<0.001$). Men reduced their emotional eating ($p<0.001$) whilst women did not ($p=0.98$). Our results suggest a change of uncontrolled eating over the 6 months period for men as well as women, but a change in emotional eating only for men.

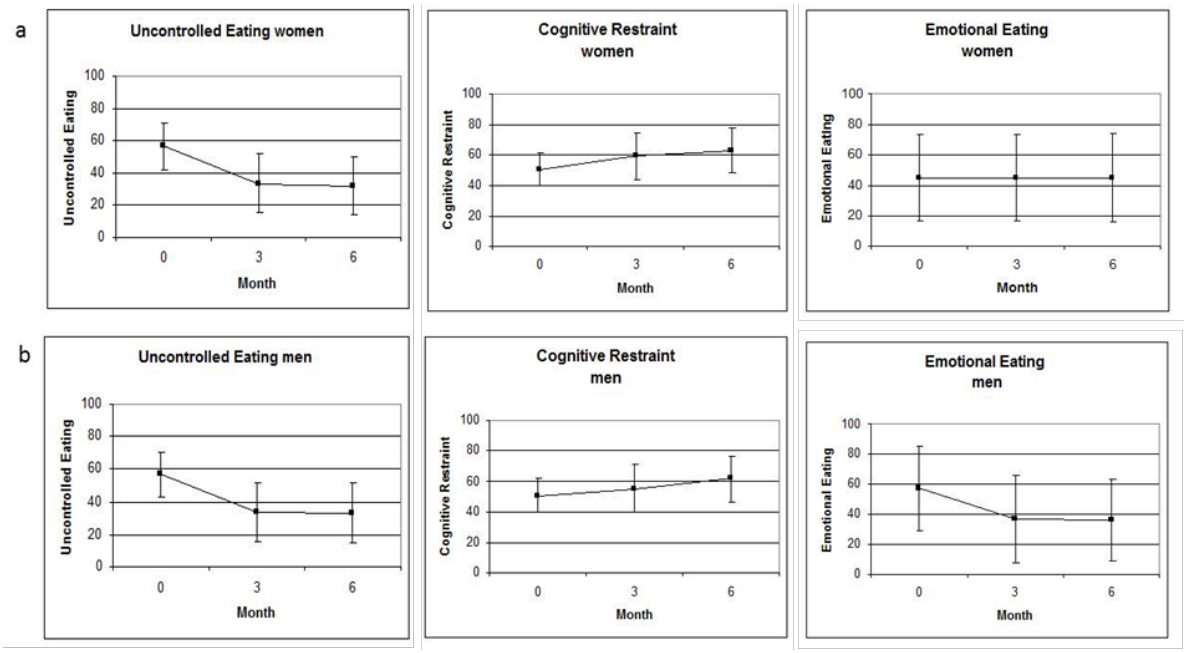


Figure 23. *Change in eating behavior over time, 6 months, a. women (n=524), b. men (n=96)*

The negative correlation between weight loss and emotional eating scores over time (women: r=–0.12, p=0.01; men: r=–0.24, p=0.02) suggest that reduced emotional eating are associated with weight loss. Uncontrolled eating correlated negatively to weight loss but only significantly for women (women: r=–0.11, p=0.02; men: r=–0.19, p=0.07) there may therefore be an association between reduced uncontrolled eating and weight loss. The scores for cognitive restrained eating increased for both genders over time and positively correlated to weight loss for the women but not the men (women: r=0.11, p=0.01; men: r=0.3, p=0.80), suggesting a possible association between an increased cognitive restrained eating score over 6 months and weight loss in women.

Women who increased their cognitive restrained eating had the greatest weight loss of –9.2% (5.3) (p=0.024). Men who decreased their emotional eating score achieved the greatest weight loss of –11.1% (5.4) (p=0.037).

There was no significant correlation found between activity on line (log-ins) and change in eating behavior over the 6 months period, neither for women or men.

4.4 PAPER IV

There were no significant differences in age, gender, co-morbidity, education, occupation and type of surgical procedure between the control group and the intervention group. At baseline, for all participants the mean weight was 115.1 (18.5) kg and the mean BMI was 40.5 (5.5) kg/m^2. The percentage of women were 78%, and the mean BMI at baseline were 40.4 (5.6) kg/m^2 and the corresponding BMI for men were 41.0 (4.9) kg/m^2. The distribution of type of surgical procedure were gastric bypass 80.8% (n=118) and the remaining 19.2% (n=28) had a sleeve gastrectomy procedure performed.

There was a gender difference in education, women had a higher education than men. Also, in some co-morbidity we found gender differences. Men more often had treatment for hyperlipidemia, hypertension and obstructive sleep apnea syndrome (CPAP treatment), while women more often were treated with antidepressants.

Moderate-to-vigorous physical activity (MVPA), including all participants, were at baseline and 18-weeks after surgery 33.4 (25.6) vs. 34.3 (26.9) minutes/day. The MVPA restricted to completers (n=69) were at baseline and 18-weeks after surgery 33.4 (26.5) and 34.5 (27.5) minutes/day, see Table 6. The completers in the intervention group increased their MVPA with 9.1 minutes/day, while the corresponding completers in the control group reduced their MVPA with -7.3 minutes/day (p=0.007).

Table 6. *Accelerometer-measured[1] moderate-to-vigorous physical activity (MVPA) among completers[2], minutes/day.*

	All (n=69)			**Intervention group**[3] (n=35)			**Control group** (n=34)			**p-value**
	Mean	SD	Min-max	Mean	SD	Min-max	Mean	SD	Min-max	
Baseline	33.4	(26.5)	1.1-140.8	31.8	(26.4)	1.1-140.8	35.2	(26.8)	4.4-108.0	0.60[4]
18-weeks	34.5	(27.5)	2.8-151.9	40.9	(32.4)	2.8-151.9	27.9	(19.6)	3.5-104.6	**0.001**[5]
p-value[6]		0.69			**0.007**			0.06		

[1] Measured using wrist-worn ActiGraph wGT3x-BT. Analysed through R-package GGIR 2.0-0, MVPA-threshold 100 mg.
[2] Accelerometer data at both measurements
[3] 12 weeks physical activity intervention delivered through the smartphone application PromMera.
[4] Independent t-test, significant if p≤0.05
[5] Analysis of covariance (ANCOVA), significant if p≤0.05
[6] Paired t-test, significant if p≤0.05

In ANCOVA analysis, the intervention group had higher levels of MVPA at 18-weeks after surgery compared to the control group, 40.9 (32.4) respectively 27.9 (19.6) minutes/day (p=0.001). The difference between the intervention group and the control group remained when all participants (completers and non-completers; n=82) with any wear time (accelerometer data) were included in the analysis (p=0.004).

In the intervention group, 54% reached the WHO goal in MVPA of 150 minutes/week at baseline and 74% at 18-weeks post-surgery (p=0.035), the corresponding numbers for the control group were 65% and 62%, respectively. The same trend was seen in the intervention goal of 210 minutes MVPA/week, were the intervention group increased the number of participants from 43% at baseline to 69% at 18-weeks (p=0.013). The numbers in the control group for the goal of 210 minutes MVPA/week were 44% and 38%, at baseline and 18-weeks respectively. The WHO recommendation of 150 minutes of MVPA/week was achieved by 59% at baseline and 68% at 18-weeks after surgery among all completers.

We found no difference in weight loss between the control group and the intervention group either at 6- or 18-weeks after surgery.

From the PromMera app we could retrieve all recordings of physical activity made by the participants during the 84 days long intervention period. Participants that logged into the app and recorded their physical activity 12 times in total, at least once per month, or minimum 20 times in total during the 12 weeks of intervention, were classified as “users” 92% (n=74). There were in average 53 (23) recorded days per user with a range between 12 and 84 days. The physical activity recorded in the PromMera app were moderate physical activity, mean 253 (45-733) minutes/week.

5 DISCUSSION

5.1 MOTIVATORS AND EXPECTATIONS

Beside weight loss, health concerns, co-morbidity, physical functioning, and appearance have been shown to be main motivators to seek bariatric/metabolic surgery (108). Whereas appearance seems to be a strong reason for women to seek bariatric surgery, men were more likely to refer to co-morbidity as a motivating factor for surgery (44, 94). In our international multicenter study, we found that the main reason to seek bariatric surgery is, as expected, weight loss. There were however regional differences and in Finland and Germany, the most reported reason was reduced co-morbidity.

The main reason to seek surgery may also reflect upon the individual patient's situation. The odds to report reduced co-morbidity and less medication were higher for those patients with a preexisting co-morbidity, or if you had children, than for those that did not have a known co-morbidity or children. That the everyday life and opportunities of people with obesity are affected has been demonstrated previously, for example the chances of being employed decrease in the population with BMI >40 kg/m^2 (109). In our study we did not see any difference in odds ratio for a certain reason to seek surgery depending on a BMI above or below than 40 kg/m^2, we did, however, see that participants without employment rated the chance of being employed more often than those with a current employment.

In the aspect of weight loss, patients and health professionals know that bariatric surgery is the treatment with the best long-term results today. Even though, to optimize the weight loss and prevent weight regain, there are changes in lifestyle required among the patients undergoing bariatric surgery. Despite that, there are studies suggesting perceived expectations in patients that surgery alone will reduce their weight, improve their physical and mental wellbeing (110, 111). When asking the study participants in Paper I how much of their weight loss would be due to surgery, the participants in Germany and the Netherlands in a greater extent expected that surgery alone would achieve the weight loss than the participants in the Nordic countries.

Unrealistic expectations on post-surgical weight loss result is also well known. If the patients lose 60% of their excessive weight it is considered a good surgical result (12). In paper I, the

group with BMI more than 50 kg/m^2 had more realistic expectations on weight loss post-surgery then those with a BMI less than 40 kg/m^2. To report satisfaction in Paper II a loss of 80% of excessive body weight was needed. Theunissen et al. reports a gender difference in expectations and achieved weight loss. In women, higher expectations were positively associated with weight loss, indicating a greater weight loss as a result of higher expectations pre-surgery (112). The main reasons to seek surgery for both genders were health concerns.

5.2 LIFESTYLE FACTORS

Eating behavior

Eating behavior undoubtedly play a role in obesity and using the Three Factor Eating (TFEQ) questionnaire have revealed some changes associated with obesity. Men with overweight were three times more likely to report high scores of emotional eating according to Ozier et al. while others reported more emotional eating among women (32, 113, 114). Higher scores of emotional eating is also found among people currently on a diet or who previous kept a diet than among those who never kept a diet (115). In baseline data from the PromMera study (unpublished) we found no significant differences in eating behavior measured by TFEQ-R21 between the group of participants with BMI less than 39.3 kg /m^2 and the group with BMI more than 39.3 kg /m^2.

In study III in a large cohort of members in a Web-based weight loss club we could see a change in eating behavior over the 6-month period of follow-up. There was also an association between change in eating behavior and a greater weight loss.

We found gender differences in the change of eating behavior, where men decreased both uncontrolled eating and emotional eating and increased their cognitive restrained eating. Women also had a decrease of uncontrolled eating and an increase of cognitive restrained eating while their emotional eating remained at the same level. Women with the greatest weight loss had increased their cognitive restrained eating score while men had decreased their emotional eating score.

Changes in the eating behavior after bariatric surgery (Roux-en-Y Gastric Bypass) measured by TFEQ is shown by Laurenius et al. (38) and similar changes also comes with biliopancreatic diversion with duodenal switch (116). Emotional and uncontrolled eating are significantly decreased after surgery while cognitive restraint eating was decreased only at the 6-weeks check-up after surgery.

The altered anatomy after bariatric surgery gives surgical patients an advantage to those receiving traditional or medical treatment (117). There are mechanisms added by surgery that

a weight loss program does not include. After surgery patients most often experience less hunger/increased satiety, an increased energy expenditure and an altered taste perception (117-119). A systematic review by Ahmed et al. (117) concludes that taste changes after bariatric surgery may serve as a factor contributing to the long-term weight loss results compared to traditional weight loss programs.

The perceived feeling of control of your eating behavior before and after bariatric surgery may also have an impact on the result. Engström et al. (120) studied the patients' sense of control over eating after surgery and found that those patients with less sense of control 2-years after surgery were those with less successful weight loss results. This group also had less improvement in health-related quality of life.

In a survey by *Hälsa oberoende av storlek* (HOBS) where 423 persons who had undergone bariatric surgery answered questions about expectations and satisfaction. More than 40% experienced that the new diet and eating schedule were challenging compared to about 30% that thought it was an easy change of habit. There was also a group that did not think it was neither easy or challenging to change their eating habits (121).

Change in level of physical activity after surgery

To have a level of physical activity within the recommended 150 minutes/week is beneficial for everyone to maintain good health, independent of weight class. If the purpose is to maintain weight loss and/or prevent weight regain an increased level of moderate physical activity to at least 200 to 300 minutes/week is necessary (122). There has also been shown that breaks of sedentary time give good metabolic effect, in terms of effect on glucose and lipid metabolism. This is of special interest in individuals with low physical activity or type 2 diabetes (123). To improve the metabolic effect in individuals with regular physical activity at baseline, you need to break sedentary time with moderate or vigorous intensity.

Among patients undergoing bariatric surgery adherence to lifestyle changes are higher during year one and two after the operation (124). The level of physical activity is perceived as higher by the patients than objectively measured with accelerometers (76, 125). An increased level of

physical activity is suggested to be beneficial for long-term weight loss and positive health effects after surgery (126, 127). On the other hand, Carretero-Ruiz et al. (128) reports in a systematic review and meta-analysis that there is no effect of physical activity on weight loss outcome, thus the variability in existing study protocols make it hard to establish a definitive conclusion. Whether this unobtained effect depends on a low intensity of the physical activity or the time spent on physical activity is discussed by Hansen et al. (129). A combination of increased daily physical activity (light to moderate PA) and supervised exercise training (vigorous PA) could be suggested to enhance weight loss post-surgery and prevent weight regain in long-term, to address this issue an RCT would be favorable.

In a recent systematic review by Messiah et al. (130), applications of eHealth and the effectiveness for metabolic and bariatric surgery patients was studied. The included studies reported generally positive results in feasibility and acceptability from the participants of eHealth delivery pre- and post-surgery although the follow-up time was short. However, of the 38 included studies only five were RTC's, two of which were ongoing. Our study was not included.

In our randomized controlled trial PromMera, we found a significantly increased level of moderate-to-vigorous physical activity (MVPA) in the intervention group compared to the control group among those who completed. There was no significant difference in basic characteristics, gender or type of surgical procedure between the intervention group and the control group at baseline. When all participants with accelerometer data from baseline were included in the analysis there was a significantly higher level of MVPA in the control group. This leads us to question if those lost in follow-up at 18-weeks post-surgery already were more physically active and therefore had less interest to provide a second measurement with the blinded accelerometer.

We found an increase of trial participants in the intervention group who reached both the WHO goal of 150 MVPA minutes/week and the intervention goal of 210 MVPA minutes/week, but not in the control group among the completers. The fact that the participants in our study were more active than the general middle-aged Swede at baseline must be emphasised. There may be different reasons for this finding. One of which may be that patients accepted for bariatric surgery have reached a higher level of motivation, and therefore have changed their lifestyle to some extent even before surgery.

The number of recordings in the PromMera app per participant ranged from 12 to 84 during the 84-day long intervention and the mean recorded minutes of moderate physical activity were more than 250 min/week during the entire period. Over 90% of the participants in the intervention group who had access to the PromMera app were classified as “users” and among those the mean number of recordings suggest a reasonable compliance to the app. The PromMera app was developed with a layout that was easy to comprehend, and to increase the feasibility and compliance for an intervention with mHealth a user-friendly app is vital.

To have a theory-based intervention is supported by previous research (83), and mHealth may serve as a promising tool for personalized interventions, not only in physical activity. In our study, there was no possibility to personalize the daily reminders from the app but you could set your own weekly goal of physical activity and get weekly feedback on your achievement.

To objectively measure physical activity with accelerometers, adds strength to the PromMera study. Today’s literature include studies with a variety in how the accelerometer is handled and how data is collected. This presents some difficulties when comparing the results, for example if the accelerometer is worn on the hip or the wrist. A wrist worn accelerometer is an acknowledged method that can collect more information about the physical activity 24/7. However, even if the accelerometer is worn on the wrist there are reported differences whether your wear it on your dominant or non-dominant wrist. Some report an overestimation of MVPA when the accelerometer is worn on the dominant wrist (131), other conclude high similitude between dominant- and non-dominant wrist variable output when using GGIR (132). Further research is needed to establish a standard for measurement and reporting accelerometer data within this.

5.3 SATISFACTION AND HEALTH RELATED QUALITY OF LIFE

Expectations and satisfaction can be assumed to be closely linked, the fulfilment of expectations may influence patients' satisfaction with the surgical result and it is therefore of importance to address those pre-surgery. Expectations of the result of surgery is routinely addressed in other areas like orthopedic surgery. In joint surgery, there are reports of 20% of patients not being satisfied after total knee arthroplasty and that unfulfilled pre-surgical expectations affect patients' level of satisfaction post-surgery (133, 134). The importance of a pre-surgical assessment of patients' expectations on the surgical result is stressed by Lützner et al. (135).

In Paper II, the post-operative satisfaction with weight loss was associated to the extent of lost excessive weight. The participants who reported satisfaction with the surgical outcome had a mean loss of more than 90% of their excessive weight. Even so, those who were unsatisfied with their weight loss had a mean loss of weight over 80% of their excessive weight.

This study sample was rather healthy even before surgery but even so, the major co-morbidities, such as musculoskeletal pain and/or arthrosis and psychiatric disorders were almost dimidiated. This was also reflected in the quality of life results where an improvement in the mental component summary scale in 86.5% and an even higher score of general health of 94.6% was found one year after surgery. We did not find any significant difference in quality of life between the satisfied and unsatisfied participants. A recently published 5-year follow-up in Norway by Hegland et al. reports that dissatisfaction is associated with lower mental health-related quality of life (HRQoL) and obesity-related HRQoL, and a higher BMI (136). They did not conclude whether this was a result associated to the fact that some of the patients had a duodenal switch and the remaining a Laparoscopic Sleeve Gastrectomy resection (LSG) and those who were unsatisfied to a larger extent had had a LSG and less weight loss.

Data from the valid national data register SOReg analyzed by Raoof et al. presents correlations between age and weight loss, and improvements in HRQoL (137). Younger patients had a higher improvement rate of their HRQoL as did those with a greater weight loss. They also found that patients with treatment for depression and those who had experienced complications to bariatric surgery reported a lower improvement rate in HRQoL.

Unrealistic expectations of the result of bariatric surgery may lead to disappointment and dissatisfaction among the patients post-operatively. Concerns like less weight loss, less improved physical functioning than expected, negative reactions from other people etc. are among those reported to affect the level of satisfaction after bariatric surgery (138). Most patients have expectations pre-surgery on a more controlled eating behavior and also express a sense of control initially after bariatric surgery, the never-ending dieting being the past and their new life are to begin (108, 139). If or when this sense of control is lost the risk of self-blame and reduce of self-esteem can affect the wellbeing and quality of life dramatically (120, 138). Unfortunately, persisting psychiatric symptoms and inadequate eating behavior post-surgery may lead to reduced health-related quality of life (140).

In our Swedish cohort, weight loss was the main reason to seek a surgical treatment for obesity. Weight loss remained as one of the top three items of satisfaction 1-year after surgery, but the highest rated item was self-esteem. Impaired self-esteem has been proven to be common among persons with obesity and is associated with symptoms of depression (141). Improved self-esteem can thus play an important role in the post-bariatric care and when it comes to adopt new lifestyle behaviors. It takes good self-esteem to approach new activities such as going to the gym or swimming pool, etc. In a study from Christenson et al. (138) among others, patients with requested personalized supportive post-surgical care to empower and educate not only the patients but include relatives in the new lifestyle. The pre-surgical information and education may in many cases not suffice or be forgotten due to time or adverse events. To personalize post-surgery care both in content and intensity may improve patients physical and mental health.

5.4 METHODOLOGICAL ASPECTS

Validity

The external validity is a measure of how the result of a study can be generalized into the population. If a study has high external validity the results may be generalized in the population from which the study sample was chosen. This postulates that the study has few systematic errors/bias and high precision of measured variables. Validity and reliability in the questionnaires used within a study can give higher accuracy of the results.

In **Paper I**, women with obesity in five different countries were included in the study sample, this diversity may be considered to bring in a systematic error/bias to the study. This may be due to differences in selection of patients and pre-surgical evaluation processing in the five participating countries. We did see differences between the countries in BMI, weight, level of education, co-morbidities and marital status and we could have had the samples matched to each other to reduce this bias. The generalizability can be questioned in study I as only women were included and it can therefore not necessarily be applicable on men.

The internal validity is dependent on eventual occurrences of systematic errors/bias. Do we measure what we intend to measure? In **Paper I**, we used a questionnaire developed specifically for this study. As this was the first study in which the questionnaire was used, the internal validity can be questioned. In **Paper II**, we did a 1-year follow-up of the Swedish cohort from study I why the same consideration about the validity of the questionnaires can be done in **Paper II**, while the external validity may be better if we consider that the sample were representative for women with obesity in Sweden.

The large sample in **Paper III** may increase the external validity but also introduce a selection bias due to the voluntary participation in the weight loss program. Those who sign up for such programs are not necessarily representative for persons with obesity in general. To improve internal validity in a questionnaire, study the use of validated questionnaires should be considered.

A randomized controlled trial (RCT) is one way to ensure validity but only if there is a low risk of systematic errors/bias. If the RCT comprises a representative study sample from the intended population and few errors of measurement are introduced, there will be a higher generalizability. The patients in **Paper IV** were referred from the whole Region Östergötland, meaning that there were patients both from urban and rural areas recruited to the study, which may give a higher external validity. To ensure the internal validity, a validated questionnaire was used as well as validated and objective measurement of physical activity with accelerometers.

Confounding

A confounding factor is associated with the exposure and can therefore affect the outcome. There are ways to avoid confounding, for example to conduct randomized controlled trials, to have matched controls in cohort studies, to stratify or adjust for possible confounders.

Paper I: There is a possibility that the difference in the surgical evaluation process between the countries could influence the outcome of the questionnaires. For example, if the patients included in Finland and Germany had a higher incidence of co-morbidities and therefore reached an increased level of danger for themselves due to their obesity, that would reflect on their reasons to seek surgery. A healthier and younger patient may have other reasons to seek surgery. One way to avoid this would have been to match the participants in all five countries, we could have matched the participants in age, BMI, co-morbidity, education, and occupation. However, the inclusion rate would then have been slowed down and required increased coordination between our centers which the available resources did not extend to.

Paper II: In this study, all the participants had the same gender and the same exposure, i.e. bariatric surgery, and we could not see that age affected the outcome.

Paper III: All participants had the same exposure i.e. viktklubb.se, in one previous analysis it was evidenced that age did not influence the result and we could show that gender may have significance but not for the weight loss but for altered eating behavior. However, we excluded participants who lost > 30% as they could have a potential confounder like bariatric surgery or disease that resulted in weight loss. Seven participants were excluded due to that. In the analyzes we stratified for gender and completers/non-completers.

Paper IV: Randomized controlled trials are done to avoid the confounding effect of both known and unknown confounders.

Information bias

Systematic errors or bias can occur if the collected data contains errors or if the study subjects are not representative of the population you want to study. In questionnaire studies, there is also a risk of recall bias meaning that the participants do not answer the questions in the anticipated way due to misunderstanding. There is no way to adjust for information bias in an analysis as they will be unevenly distributed.

Paper I: To avoid the risk of incorrect reporting of comorbidity we cross checked the answers with the medical records. Our questionnaire was new and not validated in different populations which could have increased the risk of information bias if the respondent had misunderstood the questions, which could lead to recall bias. For example, we discussed whether we could use the BAROS questionnaire to measure quality of life (142), but due to differences in social interaction between the countries that was deemed to be less appropriate.

Paper II: We cross checked co-morbidity with medical records to reduce the risk of incorrect reporting and a recall bias. A reason to test the questionnaire in persons with obesity before conducting the study was to avoid information and recall bias.

Paper III: In this study there is a risk of recall bias. The participants self-reported their weight, even though this error would be the same at all measuring points if the participant weigh themselves using the same scale at all time points. To minimize a bias like this you either need to have the participants come into the hospital for weight measurement or distribute a valid scale to their homes. Either way would require more resources.

Paper IV: If we had relied on self-reported levels of physical activity, there would have been a risk of over-reporting by participants which may affect the results in a study with the intention to stimulate to an increased physical activity. This was avoided by using objective measurements of physical activity with accelerometers. We used a validated questionnaire to minimize the risk of information and recall bias.

Selection bias

The selection of the study sample can introduce a systematic error in two ways, at first, by selection of the participant, and secondly, by factors affecting the study participant. There may be differences in the association between exposure and illness in the study sample and the group that are not included in the study. One example is that those taking part in public screening programs may not be comparable with those who chose not to, therefore, the generalizability of the results of screening programs can be questioned.

Paper I: Differences between the five countries may have occurred in this regard due to the difference in the selection and evaluation process prior to bariatric surgery. The Swedish cohort is healthier than the other cohorts, and that could be due to the selection. Patients with diabetes were at the time of inclusion offered to participate in other more extensive studies. Healthier subjects might rate differently than more unhealthy subjects in their reasons to seek surgery and satisfaction after surgery.

Paper II: Apart from the fact that a rather healthy cohort might reflect upon the rating, we cross checked the medical records of the drop outs and they did not stand out in terms of complications or weight results.

Paper III: This study recruited voluntary people with obesity from an on-line platform, they are therefore a self-selected cohort. This is of course a high risk for selection bias and must therefore be considered when drawing conclusions from the study.

Paper IV: The participants in this study is a selection of people that are owners of a smartphone and have skills to use it but since more than 90% of the Swedish population have a smartphone it might be negligible. Selection bias of patients can occur if access to health care is biased by socioeconomic factors. In Sweden, there are equal access to bariatric surgery within the public health care (143).

6 CONCLUSIONS

In **Paper I**, weight loss is the main reason for female patients to apply for bariatric surgery and patients' expectations on the surgical outcome are frequently too high regardless of country according to our study. Improvement of co-morbidity is the second most important reason. This can be useful and novel information about patients with obesity expectations on the results of bariatric surgery and may be useful in improving preoperative information for the patients and their relatives.

In **Paper II**, the primary reason to seek bariatric surgery was weight loss. Improved self-esteem was the item of most satisfaction one-year post-surgery. A weight loss of more than 80% of the participants excessive weight was required to be satisfactory. Our findings may be useful in the clinical setting when informing patients and assessing the patients' expectations pre-surgery, as well as in meeting the patients post-surgery to discuss the outcome.

In **Paper III**, the results suggest a change in eating behavior after a web-based weight loss intervention. The eating behavior, cognitive restrained eating, uncontrolled eating and emotional eating measured by TFEQ-R18 can be significantly changed during six-months of participation. Our findings indicate differences in eating behaviors with respect to sex, but should be interpreted with caution since attrition was high.

In **Paper IV**, the results in the PromMera study indicate that the smartphone application has the potential to make a small increase in moderate-to-vigorous physical activity during the first months among patients who have undergone bariatric surgery. However, there were no difference in weight loss between the group receiving standard care and the group receiving the app intervention plus standard care. mHealth may be a promising way to guide the patients during their first year after bariatric surgery in lifestyle changes such as physical activity.

To address patient expectations before bariatric surgery may improve post-surgery satisfaction, this may also apply in in non-surgical weight loss treatment. Individualized pre-surgery information and post-surgery care could be of importance for the lifestyle changes required after bariatric surgery. Technology like Web-based or app-based programs may serve as interactive solutions to support lifestyle changes and the need for personalized information in both a surgical and a non-surgical setting for weight loss treatment.

7 FUTURE PERSPECTIVES

For Paper I and II, the opportunity to perform a future follow-up in all five centers involved seems unlikely. It would be more interesting to conduct a new study with the same conditions to see if the expectations and attitudes among patients remains or if they have changed over time.

To conduct a similar study like the one in Paper III but now with mHealth would be possible though the weight club still runs both on the web and within a smartphone application. The accessibility with an app might improve compliance and decrease the attrition rate over time. An improvement would be to have a longer follow-up. One way to do that could be to let the participants register their mail address when they join the study, that gives you the possibility to send out the questionnaires even if the participants stopped logging in to the application.

The PromMera study is still running and the last participant for 1-year follow-up will be in late September 2020. During the fall 2020 we will analyze the data of physical activity, HRQoL, eating behavior, body composition etc. Later there will be data from the 2-year follow-up.

In respect of the results from the four included studies, a study with an app designed for post-bariatric care would be exciting. The app could address both medical care, eating behavior and physical activity. If the patients were able to adjust the app for their individual need and set their reminders as it fits them it might fulfill the patient satisfaction even more. To enable contact with nurses, dieticians and physicians or even peers through the app would give the patients more support and may improve their compliance to a new lifestyle after surgery.

Another subject of interest is how the participants in the intervention group experienced the app intervention period and time period after the 12-weeks long intervention. This would be an issue to address with a qualitative interview study. Did the PromMera app notices support them in their physical activity and intake of vitamins and mineral supplement? Was this a positive treat or did this stress them? Would a peer group within the app been of value or a possibility to chat and ask the health care professionals questions on line? Would notices or meal schedule within the app been of help? There are many questions to raise and explore in this area of health care to improve and personalize the care for this group of patients.

8 POPULÄRVETENSKAPLIG SAMMANFATTNING

Obesitas-kirurgins utmaning – betydelsen av livsstilsförändring och adekvat information för att förbättra patientens livskvalitet och hälsa

Enligt Världshälsoorganisationen (WHO) har antalet personer med obesitas eller övervikt ökat dramatiskt världen över under de senare decennierna. WHO menar att de flesta människor idag lever i länder där övervikt och obesitas är en större risk för livshotande tillstånd än undervikt. Eftersom det finns ett vetenskapligt fastlagt orsakssamband mellan obesitas och andra sjukdomar som diabetes, högt blodtryck, hjärtkärlsjukdom och cancer har ett ökat fokus på viktminskningsprogram och även på metoder som kirurgi för viktminskning tillkommit inom sjukvården och samhället.

Viktminskningsprogram med beteendemodifikation är traditionellt sett den vanligaste behandlingen men dess långtidsresultat har inte varit så övertygande och detta har bidragit till obesitas-kirurgins exponentiella ökning för patienter med BMI ≥35 kg/m^2 i Sverige. Men det är känt att även för de patienter som genomgår obesitas-kirurgi har livsstilsförändringar betydelse för att bibehålla en tillfredställande viktminskning på lång sikt.

Obesitas påverkar inte bara individen utifrån ökad risk för sjuklighet utan även form av nedsatt livskvalité vilket man har sett förbättras både efter viktminskningsprogram och obesitas-kirurgi. Att bibehålla viktminskningen långsiktigt ökar patienternas nöjdhet men också individens självkänsla och livskvalité.

I den här avhandlingen har vi visat att viktminskning och minskad sjuklighet till följd av obesitas är bland de viktigaste skälen till att man vill genomgå en obesitas-operation. Men patientens livssituation påverkar också av vilken anledningen man söker sig till kirurgi t.ex. de som har diabetes eller annan komplikation till sin obesitas anger detta i högra grad som skäl till kirurgi än de utan komplikationer. Ökad självkänsla var det patienterna i vår studie var mest nöjda med ett år efter operationen utöver sin minskade vikt.

E-hälsa är ett nytillskott inom sjukvården som ger möjlighet att nå patienter mer kostnadseffektivt och med en mer individualiserad approach. E-hälsa kan förmedlas på flera sätt antingen bland annat via Internet eller via en app i en smarttelefon. Vi har visat att deltagare i en Internet-baserat viktminskningsprogram förändrat sitt ätbeteende i favör till viktminskning över sex månaders deltagande även om det inte är visat att effekten är bestående över längre tid än sex månader.

Ökad fysisk aktivitet är något som förbättrar hälsan för människor oavsett vikt. WHO rekommenderar att man ska röra på sig med medelhög till hög intensitet minst 150 minuter per vecka för att bibehålla sin hälsa och vikt. För att nå viktminskning bör man öka sin dos av fysisk aktivitet till minst 210 minuter i veckan. Typen av fysisk aktivitet bör man anpassa till tycke och smak men raska promenader är ett bra och lättillgängligt alternativ som har vetenskapligt stöd.

Att komma igång med ökad fysisk aktivitet efter en obesitas-operation kan vara ett sätt att optimera sin viktminskning långsiktigt och förbättra sin hälsa. I vår studie påmindes deltagarna via en app dagligen om att vara fysiskt aktiv och registrera sin fysiska aktivitet under 12 veckor efter obesitasoperationen. Vi såg där en ökning av antalet minuter fysisk aktivitet per dag i gruppen som hade tillgång till appen jämfört med den grupp som inte hade det vid mätning direkt efter de 12 veckorna. Vi kommer att följa upp med mätning i grupperna även ett år efter operationen för att se om denna effekt kvarstår.

***Sammanfattningsvis**:*

I denna avhandling har vi visat att patienter kan ha olika skäl till att vilja genomgå obesitas-kirurgi och att det kan bero på patientens individuella hälsostatus och social status innan operationen. Vi har också visat att nöjdhet med resultatet av operationen till viss del är kopplad till hur stor viktminskningen blivit efter operationen men att ökad självkänsla också är en viktig faktor för nöjdhet. Denna kunskap kan ge vården möjlighet att möta varje patient individuellt utifrån dess personliga förutsättningar inför och efter obesitas-kirurgi. E-hälsa i form av guidning till ändrade kostvanor eller uppmuntran till ökad motion via Internet eller en app i smarttelefonen ger ytterligare möjligheter att individualisera vården då sådana plattformar kan justeras via inställningar av patienterna själva. Detta kan bidra till ökad personcentrering inom vårdkedjan både på överviktsenheter och inom obesitas-kirurgin.

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